

EXHIBIT 510

1 UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 MDL NO. 1968

5
6 IN RE: DIGITEK PRODUCT)CONTINUED
LIABILITY LITIGATION)VIDEOTAPED DEPOSITION
7)OF:
8)MARK G. KENNY
_____)X
VOLUME II

9
10
11 TRANSCRIPT of the stenographic notes of
12 The proceedings in the above-entitled matter, as
13 taken by and before JANE D. WATSON, a Notary Public
14 of the State of New York, held at the office of
15 Harris Beach, 100 Wall Street, New York, New York
16 10005 on Wednesday, February 16, 2011, commencing at
17 9:50 a.m.
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<p style="text-align: right;">Page 302</p> <p>1 A P P E A R A N C E S:</p> <p>2</p> <p>3 MOTLEY RICE</p> <p>4 28 Bridgeside Boulevard</p> <p>5 Mount Pleasant, South Carolina 29464</p> <p>6 BY: MEGHAN CARTER, ESQ.</p> <p>7 Counsel for Plaintiffs</p> <p>8</p> <p>9 SHOOK, HARDY & BACON, L.L.P.</p> <p>10 2555 Grand Boulevard</p> <p>11 Kansas City, Missouri 64108-2613</p> <p>12 BY: HARVEY L. KAPLAN, ESQ.</p> <p>13 Counsel for Mylan</p> <p>14</p> <p>15 TUCKER, ELLIS & WEST</p> <p>16 515 South Flower Street, 42nd Floor</p> <p>17 Los Angeles, California 90071</p> <p>18 BY: MICHAEL ANDERTON, ESQ.</p> <p>19 Counsel for Actavis</p> <p>20</p> <p>21 ALSO PRESENT:</p> <p>22 Chris Martin, Videographer</p> <p>23 Peter Cooper, Videographer in training</p> <p>24 Rick Fern, Esq. (in a.m.)</p> <p>25</p>	<p style="text-align: right;">Page 304</p> <p>1 THE VIDEOGRAPHER: Good morning.</p> <p>2 We're on the record. Today's date is</p> <p>3 February 16, 2011, and the time is 9:50 a.m.</p> <p>4 This is the continuation of the videotaped</p> <p>5 deposition of Mark Kenny. The caption on</p> <p>6 this case is In Re: Digitek Product</p> <p>7 Liability Litigation. Case number -- I'm</p> <p>8 sorry -- MDL number 2:09-CV-121. Case filed</p> <p>9 in the U.S. District Court, Southern</p> <p>10 District of West Virginia, Charleston</p> <p>11 Division. We're at the office of Harris</p> <p>12 Beach, 100 Wall Street, New York, New York.</p> <p>13 This deposition was noticed by Attorney</p> <p>14 Matthew Moriarty of the firm Tucker, Ellis &</p> <p>15 West. The videographer is Chris Martin.</p> <p>16 The court reporter is Jane Watson.</p> <p>17 At this time, will Counsel please</p> <p>18 introduce themselves for the record.</p> <p>19 MS. CARTER: Meghan Carter for the</p> <p>20 Plaintiffs.</p> <p>21 THE WITNESS: Mark Kenny.</p> <p>22 MR. KAPLAN: I'm Harvey Kaplan, Shook,</p> <p>23 Hardy & Bacon for Mylan.</p> <p>24 MR. ANDERTON: Michael Anderton,</p> <p>25 Tucker, Ellis & West for the Actavis</p>
<p style="text-align: right;">Page 303</p> <p>1 I N D E X</p> <p>2 WITNESS PAGE</p> <p>3 Mr. Kenny Mr. Kaplan 305</p> <p>4 Mr. Anderton 526</p> <p>5 Ms. Carter 578</p> <p>6</p> <p>7 EXHIBITS</p> <p>8 IDENT. DESCRIPTION PAGE</p> <p>9 Exhibit 110 Folder 400</p> <p>10 Exhibit 111 Chronology from disks 417</p> <p>11 Exhibit 112 E-mail 432</p> <p>12 Exhibit 113 Amended notice for video</p> <p>13 Deposition 445</p> <p>14 Exhibts 114-139 Documents brought by the</p> <p>15 Witness in milk crates 447</p> <p>16 Exhibit 140 First draft report 466</p> <p>17 Exhibit 141 Draft of expert report 482</p> <p>18 Exhibit 143 E-mails 527</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 305</p> <p>1 defendants.</p> <p>2 THE VIDEOGRAPHER: At this time, the</p> <p>3 court reporter will swear in the witness.</p> <p>4 M A R K K E N N Y, called as a</p> <p>5 Witness, having been duly sworn by a Notary</p> <p>6 Public, was examined and testified as follows:</p> <p>7</p> <p>8 EXAMINATION BY MR. KAPLAN:</p> <p>9 Q. Good morning, Mr. Kenny.</p> <p>10 A. Good morning.</p> <p>11 Q. I think we met when your deposition</p> <p>12 was taken on June 29 of last year, June 29, 2010 in</p> <p>13 Newark, New Jersey, right?</p> <p>14 A. Correct.</p> <p>15 Q. At that time, you were examined by</p> <p>16 Mr. Moriarty on behalf of Activas, right?</p> <p>17 A. That's correct.</p> <p>18 Q. He took pretty much the full day, so I</p> <p>19 didn't have a chance to ask you questions, and today</p> <p>20 is my opportunity to examine you on behalf of my</p> <p>21 client, Mylan.</p> <p>22 A. I understand.</p> <p>23 Q. How are you doing?</p> <p>24 A. I'm doing well, thank you.</p> <p>25 Q. All right. Good. I know that you had</p>

<p style="text-align: right;">Page 306</p> <p>1 recent Achilles heel surgery, and we're sympathetic 2 to your situation. And as I told you, if you need 3 breaks throughout the day, all you need to do is say 4 that you need a break and we'll do that. Okay? 5 A. Thank you. It's much appreciated. 6 Q. All right. Just as you came to the 7 deposition on June 29, 2010 prepared to give your 8 opinions in this case -- you did? 9 A. Yes. 10 Q. You came prepared at that time, didn't 11 you? 12 A. Yes. 13 Q. And you are today prepared to give 14 opinions in this case; isn't that right? 15 A. Yes, I am. 16 Q. And all the work that you did in 17 preparation for any opinions that you will offer in 18 this case are contained within your report which was 19 dated June 15, 2010? 20 A. That is correct. 21 Q. And that report is in front of you? 22 A. That is correct. 23 Q. That -- that has all of your opinions, 24 right? 25 A. That is correct.</p>	<p style="text-align: right;">Page 308</p> <p>1 A. Okay. The vast majority of them are 2 ones that are referenced in my report. One of the 3 issues if you -- 4 Q. Just -- there's -- there's a simple 5 question, and I'm going to ask you -- we'll get 6 through this a lot faster. Don't -- don't go off 7 and give me narrative answers, just concentrate on 8 the question I ask, okay? 9 A. I understand. 10 Q. So my question is -- here's the simple 11 question: You said that since your deposition was 12 taken on June 29, 2010, you reviewed some additional 13 Mylan documents? 14 A. That's correct. 15 Q. And my question is which documents did 16 you review, have you reviewed, since June 29, 2010? 17 That's all I want you to do is identify those. 18 A. They're in this particular binder. 19 Q. All right. Tell me which Mylan 20 exhibits you have reviewed since your deposition was 21 taken on June 29, 2010. 22 A. I can go through them? 23 Q. Certainly. 24 A. Okay. 25 Q. Just tell me which they are.</p>
<p style="text-align: right;">Page 307</p> <p>1 Q. You stand by that report? 2 A. Yes, I do. 3 Q. Or -- or is there anything you want to 4 withdrawal or modify? 5 A. I stand by the report. 6 Q. Stand by the report. Okay. And have 7 you done any further work since June 15, 2010 with 8 respect to -- 9 A. Yes, I have. 10 Q. What have you done? 11 A. I've looked at some of the Mylan 12 exhibits again, I reviewed them. 13 Q. Why? 14 A. To familiarize myself with the 15 documents, refamiliarize, since it was a long time 16 ago that I reviewed it. 17 Q. What -- what Mylan exhibits did you 18 look at? 19 A. I have all of the Mylan exhibits here. 20 Q. Okay. But -- but I'm interested in 21 particularly what is it that you looked at and -- 22 A. Well, I'd have to pull it and show you 23 what -- 24 Q. Well, why don't you pull it and show 25 me what you looked at.</p>	<p style="text-align: right;">Page 309</p> <p>1 A. What additional ones? 2 Q. Yes. 3 A. Which ones -- see, the -- the 4 difficulty, if I can explain something, is that 5 between the original deposition and today, I don't 6 have the original copies that I reviewed that I 7 submitted. So I went back to the computer database 8 for Mylan and I went through to see if any of them 9 were germane to my opinion. And at that particular 10 point, I made copies of those and probably copies of 11 those -- a couple that were in addition to. So, 12 anyway, going through this -- are you ready? 13 Q. Yes. 14 A. M55. 15 Q. You're referring to the exhibit M55 16 from previous depositions? 17 A. Right. 18 Q. Let me see that. M55 is an e-mail 19 from Lee Radtke to Chuck Koons dated December 13, 20 2006; is that correct? 21 A. I believe -- I'm sure you're right. 22 Q. Okay. You reviewed -- you reviewed 23 that -- that exhibit? 24 A. Yes. 25 Q. Okay. And what, if anything, did</p>

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<p style="text-align: right;">Page 310</p> <p>1 that --</p> <p>2 A. This changed nothing, nothing at all.</p> <p>3 Q. Just so we got a clean record on this.</p> <p>4 You reviewed exhibit M55, the e-mail from Lee Radtke</p> <p>5 to Chuck Koons dated --</p> <p>6 A. Dated December 13, 2006.</p> <p>7 Q. But that did nothing to change your</p> <p>8 opinion --</p> <p>9 A. Not in the least bit. Not in the</p> <p>10 least bit.</p> <p>11 Q. Didn't enlighten you in any regard?</p> <p>12 A. The only -- I would say the thing that</p> <p>13 enlightened me is that it reconfirmed when I had</p> <p>14 stated that they did not do a comprehensive audit.</p> <p>15 And he says in here, Chuck Koons, says we did a</p> <p>16 system audit, I just don't think they could handle</p> <p>17 it right now. But when I read the original report,</p> <p>18 it was very clear to me that it did not represent</p> <p>19 what the industry referred to as a comprehensive GMP</p> <p>20 audit nor would it be in accordance to the procedure</p> <p>21 that they had, which I did read.</p> <p>22 Q. Did the FDA do comprehensive GMP</p> <p>23 audits of --</p> <p>24 A. I can't tell you whether it's</p> <p>25 comprehensive or not. I will tell you they looked</p>	<p style="text-align: right;">Page 312</p> <p>1 manufacturing practice regulations are the FDA's</p> <p>2 regulations?</p> <p>3 A. They are -- I -- I suppose you could</p> <p>4 say that, yes. They are codified in the CFR.</p> <p>5 Q. And they are what you would refer to</p> <p>6 as expertly drafted law, right?</p> <p>7 A. GMPs, yes, I believe that.</p> <p>8 Q. All right. What is the next Mylan</p> <p>9 document that you reviewed since your deposition was</p> <p>10 taken on June 29, 2010?</p> <p>11 A. M53 (handing).</p> <p>12 Q. Exhibit M53 from a previous deposition</p> <p>13 which you have just handed me, is a e-mail from Lee</p> <p>14 Radtke to Chuck Koons dated October 13, 2006. And</p> <p>15 is the highlighting yours?</p> <p>16 A. Yes, every highlighting in here would</p> <p>17 be mine.</p> <p>18 Q. You've -- you've highlighted an e-mail</p> <p>19 below from Chuck Koons to Lee Radtke, you've</p> <p>20 highlighted the sentence that says, "We were already</p> <p>21 scheduled to do an on-sight audit on 11/8 and 11/9,</p> <p>22 and we're trying to get a status report on this</p> <p>23 prior to our visit." That's the only thing that you</p> <p>24 highlighted in 53, right?</p> <p>25 A. That's correct.</p>
<p style="text-align: right;">Page 311</p> <p>1 in a lot of areas.</p> <p>2 Q. A lot of times?</p> <p>3 A. A lot of times.</p> <p>4 Q. As many as 12 inspections between 1999</p> <p>5 and 2008, correct?</p> <p>6 A. Okay. If that's the number, I believe</p> <p>7 you.</p> <p>8 Q. Over a period of 182 days?</p> <p>9 A. Yes.</p> <p>10 Q. Is that right?</p> <p>11 A. If you say so. I'll agree with that.</p> <p>12 Q. You don't have any reason to disagree</p> <p>13 with it?</p> <p>14 A. No, I have no reason to disagree with</p> <p>15 you.</p> <p>16 Q. You would agree with me that the FDA</p> <p>17 extensively audited Actavis over a nine-year period?</p> <p>18 A. They inspected them, but yes.</p> <p>19 Q. And audited them?</p> <p>20 A. Well, they don't use the term "audit."</p> <p>21 Q. Extensive inspections?</p> <p>22 A. Yes.</p> <p>23 Q. GMP inspections?</p> <p>24 A. Correct.</p> <p>25 Q. In fact, it's GMP or good</p>	<p style="text-align: right;">Page 313</p> <p>1 Q. What -- what was the significance of</p> <p>2 this to you?</p> <p>3 A. Well, I had earlier wondered why it</p> <p>4 wasn't scheduled and any -- any information that I</p> <p>5 looked at what -- what referred to the audit either</p> <p>6 explaining why -- why it was going to occur or why</p> <p>7 it didn't occur was notable to me.</p> <p>8 Q. Okay. And -- and how did this exhibit</p> <p>9 M53 enlighten you?</p> <p>10 A. It had no effect whatsoever on my</p> <p>11 opinion.</p> <p>12 Q. Okay. All right. And by the way,</p> <p>13 when you -- since your deposition was taken on</p> <p>14 June 29, 2010, did you review these additional Mylan</p> <p>15 documents at one time, over a period of time? Tell</p> <p>16 me how that occurred.</p> <p>17 A. I did it -- I started two days before</p> <p>18 the first scheduled deposition for 2009.</p> <p>19 Q. 2009?</p> <p>20 A. 2010. In other words, this calendar</p> <p>21 year. So I looked at it in --</p> <p>22 Q. We're now in 2011.</p> <p>23 A. Eleven, rather, I'm sorry. In 2011, I</p> <p>24 went back to review to familiarize myself, then I</p> <p>25 realized I didn't have a lot of documents that I</p>

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<p style="text-align: right;">Page 314</p> <p>1 felt were missing, and I went back to the Crivella 2 database and I picked out some procedures or some 3 documents including only these that are here. This 4 is it. (Indicating.) This is 100 percent 5 comprehensive (indicating). 6 Q. And over a period of -- you did this 7 review over a period of days, one day -- 8 A. A period of two days. 9 Q. Two days? Okay. And that was -- 10 A. But the -- can I explain that though, 11 if I may? 12 Q. Just try to answer my questions and 13 we'll get along. So I just want to understand what 14 you did, how much time you spent, why you did it, 15 what you looked at. So what you're telling me is 16 that your deposition had been scheduled earlier in 17 2011, right? 18 A. Correct. 19 Q. Two days before your deposition had 20 been scheduled, you -- you started looking at Mylan 21 documents? 22 A. Correct. I -- I went to seek out 23 documents to refamiliarize myself with the 24 references in the report. And then I found out I 25 didn't have those documents, then I went back into</p>	<p style="text-align: right;">Page 316</p> <p>1 to refamiliarize myself with the basis of my 2 opinion. 3 Q. Okay. And so that was the purpose? 4 A. Correct. 5 Q. And it took you a day and a half to 6 find the documents and print them, right? 7 A. Approximately. 8 Q. And you -- you charged for -- for 9 that, right? 10 A. I have not charged for it. I'm -- 11 Q. It's to be billed? 12 A. Yeah, yeah. But I'm not sure exactly 13 what the bill is going to be. 14 Q. So a day and a half, is that 12 hours? 15 A. That's 12 hours, yeah. 16 Q. Okay. At \$430 an hour? 17 A. Yeah. It's actually much more than 18 that, but I will not bill because I feel somewhat 19 culpable perhaps in not having these documents. 20 Q. So a day and a half to find the 21 documents and print them, and then two hours to 22 review them? 23 A. Approximately, yeah. And that 24 maybe -- 25 Q. So the two hours is also at \$430</p>
<p style="text-align: right;">Page 315</p> <p>1 the database for Mylan because I knew that the next 2 deposition was going to be focused on Mylan, and I 3 started looking at the documents and the numbers and 4 I made copies of anything that looked even remotely 5 close to the subject that I had put into my report. 6 Q. Okay. And how long did you spend 7 reviewing the Mylan documents? 8 A. I spent a day and a half printing the 9 documents and finding them. I spent another prior 10 to that, probably two hours reviewing the documents. 11 Q. So it took you a day and a half to 12 find the documents that are in this notebook in 13 front of you? 14 A. Right. I was panicking, so to speak. 15 Q. Okay. So it was two days before your 16 deposition was scheduled, you were panicked? 17 A. Yes. 18 Q. Because you knew I was going to be 19 asking you questions. 20 A. Correct. 21 Q. About Mylan? 22 A. Right. 23 Q. And you said, gosh, I got to go back 24 and beef up here, right? 25 A. Beef up is not the right term. I have</p>	<p style="text-align: right;">Page 317</p> <p>1 dollars an hour, right? 2 A. That's correct. 3 Q. By the way, \$430 an hour, is that the 4 highest billing rate that -- that you have on any 5 matter that you -- you're working on? 6 A. The highest billing rate -- when it's 7 a rate, yes. 8 Q. And I believe you testified previously 9 when your deposition was taken on June 29, 2010 that 10 you worked for various clients at \$250 an hour? 11 A. Two -- over 300. 12 Q. Or \$300 an hour? 13 A. Three hundred ten, 12, depending on 14 where I'm at. 15 Q. But for -- for the purposes of being 16 an expert witness in this case, you decided that you 17 could charge \$430 an hour? 18 A. Correct. 19 Q. And you're being paid at that rate? 20 A. That is correct. 21 Q. Okay. We'll get into -- I want to 22 clean up the payments and all. 23 A. Sure. 24 Q. We'll probably do that at the end. 25 Okay. So now -- now we know what you did. You</p>

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<p style="text-align: right;">Page 318</p> <p>1 looked at documents two days before your deposition 2 was originally scheduled in 2011. It was then 3 continued to eventually today, right? 4 A. Yes. 5 Q. But -- but the only time that you did 6 any additional work was what you've just described; 7 is that right? 8 A. That is correct. 9 Q. The two days before that deposition 10 was scheduled? 11 A. Yes. 12 Q. It was canceled? 13 A. Correct. 14 Q. And continued? 15 A. Correct. 16 Q. Okay. But you've done nothing since 17 then? 18 A. Since that time, yes, I did. 19 Q. Oh, okay. What -- what -- and what 20 have you done? 21 A. I spent approximately eight hours now 22 reviewing the documents that I had made copies of 23 and re-reviewing all of the referenced documents 24 that were in the -- referenced in the -- the expert 25 report.</p>	<p style="text-align: right;">Page 320</p> <p>1 that the documents you just reviewed three days ago 2 are not the same documents that you reviewed before 3 your deposition was to be originally taken earlier 4 in 2011. Am I right? 5 A. I don't recall, because some of the 6 documents I looked at electronically. In this case, 7 I ended up printing anything that had anything to do 8 with the wording in my deposition because I wanted 9 to make sure -- sir, the way that unfortunately the 10 copies were made, there were many, many Mylan 11 documents which didn't have M numbers on them, they 12 had another number. So -- and so in my report, 13 there are Mylan documents referred ATA or ATV, or 14 they could be plaintiff 1, 2, 3, 4. And I had no way 15 without -- I mean, each one took 45 minutes to 16 figure out which was the right copy, therefore, I 17 made copies of anything that was related to it, 18 which appears in here. This is 100 percent. Or 19 there could be something in there (indicating). But 20 these were more, I would say pertinent. Then I had 21 to read these in order to see if they were the right 22 P documents or ATA documents. So I had a process. 23 Q. I got you. I understand. In addition 24 to reviewing the documents contained in the notebook 25 in front of you, have you done anything else in</p>
<p style="text-align: right;">Page 319</p> <p>1 Q. Was that in that two days before your 2 deposition was originally scheduled? 3 A. The second time. This is two days 4 before -- let's say three days ago, in essence, 5 three days ago. 6 Q. Okay. Okay. So there was the initial 7 re-review of Mylan documents? 8 A. Yes. 9 Q. Two days before your 2011 deposition 10 was to be taken? 11 A. There was a two hour review, yes. 12 Q. Okay. Two hour review after a day and 13 a half spent finding and printing documents, 14 correct? 15 A. Yes. 16 Q. And then three days ago? 17 A. Yes. 18 Q. You spent another eight hours 19 reviewing these documents? 20 A. That is correct. 21 Q. The same documents? 22 A. The same documents and the ones that 23 are in here that we -- you wanted to go through. 24 Q. When you say the same documents and 25 the ones that are in here, that leads me to believe</p>	<p style="text-align: right;">Page 321</p> <p>1 preparation for this deposition? 2 A. No. 3 Q. Have you talked to Ms. Carter or any 4 of the Plaintiff's lawyers? 5 A. Nobody, no human being, not even my 6 wife. 7 Q. Well -- all right. So you haven't had 8 any conversations with any of the Plaintiff's 9 lawyers about anything related to preparation for 10 this deposition today? 11 A. No. Yesterday, I met with Meghan for 12 a period of approximately four hours of which we 13 probably spent a half hour talking and I spent three 14 and a half hours or so trying to, again, mentally 15 organize myself. 16 Q. You met with -- with Ms. Carter 17 yesterday for four hours? 18 A. Yes. 19 Q. In preparation for your deposition? 20 A. Correct. We met for about a half 21 hour -- 22 Q. What did she tell you? 23 A. She gave me -- she said it's, you 24 know, expect the same type of questions. Expect 25 that since Harvey didn't have an opportunity --</p>

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<p style="text-align: right;">Page 322</p> <p>1 yourself, Mr. Kaplan. 2 Q. Harvey is fine. 3 A. Didn't have an opportunity -- okay. 4 Didn't have an opportunity to ask you questions, he 5 will ask questions about Mylan. And you just want 6 to make sure you are familiar with the documents. 7 That was the extent of our conversation. 8 Q. Well, did you have any specific 9 discussions about any specific issues related to 10 Mylan? 11 A. Zero. 12 Q. Zero? 13 A. Zero. Absolutely zero. 14 Q. So what did you do for the three and a 15 half, four hours? 16 A. We talked a lot about different stuff. 17 Q. But that's at \$430 an hour. 18 A. Sir, you're talking about two 19 different things. \$430 an hour is my rate. What I 20 bill is not my total hours put into a project. 21 Never, ever, have I ever billed at what actually 22 I've put in. I have always billed less than, not 23 even equal to it, just because I feel my efficiency 24 may not be 100 percent. I should be billing when my 25 efficiency is 100 percent.</p>	<p style="text-align: right;">Page 324</p> <p>1 A. Correct. It takes about two hours 2 door to door to get here and about two hours to get 3 back. 4 Q. Okay. Did you discuss any of your 5 opinions as to Mylan with Meghan yesterday? 6 A. No, none at all. 7 Q. Did you review these documents with 8 Meghan? 9 A. No. The only -- she didn't look at 10 the documents but I explained to her that -- 11 Q. When I say Meghan, I'm sorry. We're 12 being a little informal. 13 A. Yeah. I understand. 14 Q. We're all on kind of a first name 15 basis. 16 A. I explained to her that I had gone 17 back to the Internet to see if there were any 18 references in warning letters or the like concerning 19 quality agreements or audits to see if specifically 20 the FDA issued warning letters that clearly outlined 21 or inferred that quality agreements and quality 22 audits were quite specifically a GMP requirement. 23 Q. And did you find any? 24 A. Yes, I did. 25 Q. You did? And are those --</p>
<p style="text-align: right;">Page 323</p> <p>1 Q. Were you efficient yesterday? 2 A. Was I fishing? 3 Q. Were you efficient? 4 A. Was I efficient yesterday, no, not 5 particularly. 6 Q. You weren't? 7 A. No. 8 Q. So for the four hours that you spent 9 with Meghan yesterday, how much are you going to 10 bill for? 11 A. I haven't decided. 12 Q. Okay. So you could bill up to four 13 hours at \$430 an hour? 14 A. Oh, no. I could bill up to my travel 15 time, an hour and a half to get there, an hour and a 16 half to get back. I could -- I could -- I'll have 17 to look back, see what I accomplished, and determine 18 whether or not I bill for eight hours. 19 Q. Oh, okay. So you may bill for eight 20 hours? 21 A. That is a possibility. 22 Q. Yesterday? 23 A. Yes. 24 Q. Okay. Because you came over here to 25 Manhattan?</p>	<p style="text-align: right;">Page 325</p> <p>1 A. They are not here, but I'll show you 2 them in a minute, if you'd like. 3 Q. You're saying that you found documents 4 from the FDA saying what now? 5 A. That there was a warning letter on a 6 company associated with not having quality 7 agreements and/or not performing audits. 8 Q. Was that on Mylan? 9 A. No. That's on other industry 10 companies, drug companies. 11 Q. What was the context of the FDA 12 document that you're talking about that -- 13 A. Would you like me to show you? 14 Q. Well, just first answer my question. 15 A. Surely. 16 Q. Okay. Give me the context. You said 17 you found an FDA document or documents regarding a 18 warning letter issued to a company for not having a 19 quality agreement or -- or not performing? 20 A. Audits. G&P audits. 21 Q. Okay. Give me the context of that. 22 When, was the company? 23 A. I would have to pull the document to 24 do that. 25 Q. What's your best recollection?</p>

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<p style="text-align: right;">Page 326</p> <p>1 A. I would like to pull the document.</p> <p>2 Q. Let me just ask you, what's your best</p> <p>3 recollection right now?</p> <p>4 A. My best recollection is I was looking</p> <p>5 at drug companies that were inspected that received</p> <p>6 warning letters. There were three or four that I</p> <p>7 saw on the screen, I printed two of them.</p> <p>8 Q. But -- but the drug company -- let me</p> <p>9 just ask you this: So you're saying you pulled</p> <p>10 something from the Internet?</p> <p>11 A. Yes.</p> <p>12 Q. Warning -- there were two warning</p> <p>13 letters that you found?</p> <p>14 A. Correct.</p> <p>15 Q. From the FDA to a manufacturer?</p> <p>16 A. To a manufacturer, correct, and a</p> <p>17 contracting company.</p> <p>18 Q. What's a "contracting company"?</p> <p>19 A. A company who is the sponsor.</p> <p>20 Q. When you say "the sponsor," what do</p> <p>21 you mean by "the sponsor"?</p> <p>22 A. One company sells the product with</p> <p>23 their name on it, the other company makes it for</p> <p>24 them.</p> <p>25 Q. When you say "the sponsor," who is the</p>	<p style="text-align: right;">Page 328</p> <p>1 company that owns or holds the ANDA?</p> <p>2 A. No.</p> <p>3 Q. What is an ANDA?</p> <p>4 A. Abbreviated new drug application.</p> <p>5 Q. What is the difference between an ANDA</p> <p>6 and an NDA?</p> <p>7 A. Sir, you're going beyond my expertise,</p> <p>8 you're going into regulatory affairs areas.</p> <p>9 Q. All you have to say is I don't know.</p> <p>10 A. I don't know.</p> <p>11 Q. Okay. Is that your answer?</p> <p>12 A. I don't have an expert opinion on</p> <p>13 that. I don't know.</p> <p>14 Q. Okay. But I just want your honest</p> <p>15 answer. If you don't know, just say you don't know.</p> <p>16 A. I don't know.</p> <p>17 Q. And you told me before, you said the</p> <p>18 term sponsor means the company that sold the product</p> <p>19 and the contracting company is --</p> <p>20 A. The company that manufactured the</p> <p>21 product. The contractor or contracting company.</p> <p>22 Q. As -- as to DIGITEK, who is the holder</p> <p>23 of the ANDA?</p> <p>24 A. I believe it's Actavis from the</p> <p>25 records that I read.</p>
<p style="text-align: right;">Page 327</p> <p>1 sponsor?</p> <p>2 A. It would be the company that sold the</p> <p>3 product.</p> <p>4 Q. What are they sponsoring?</p> <p>5 A. It's just a term that is sometimes</p> <p>6 used. It's the manufacturer -- it's the name that's</p> <p>7 on the label.</p> <p>8 Q. The name that's on the label of what?</p> <p>9 A. Of the product.</p> <p>10 Q. Is that the holder of the NDA?</p> <p>11 A. I don't know.</p> <p>12 Q. What -- what do you call the holder of</p> <p>13 an NDA or an ANDA?</p> <p>14 A. I don't know what the official term</p> <p>15 is. The holder of the NDA.</p> <p>16 Q. You don't know?</p> <p>17 A. I don't know what the formal term is.</p> <p>18 Q. In all of the years that you were with</p> <p>19 Johnson & Johnson in the drug industry, you don't</p> <p>20 know what you call the company that holds the NDA?</p> <p>21 A. We'd say it owns the NDA.</p> <p>22 Q. What?</p> <p>23 A. The company that owns the NDA. It's</p> <p>24 what I would call it, perhaps it's an informal term.</p> <p>25 Q. And you don't know what you call the</p>	<p style="text-align: right;">Page 329</p> <p>1 Q. And who is the manufacturer DIGITEK?</p> <p>2 A. The manufacturer is Actavis.</p> <p>3 Q. What is the significance of Actavis</p> <p>4 being the holder of the ANDA as to GMP compliance?</p> <p>5 A. Well, they need to, as all companies</p> <p>6 do, need to comply with GMP. I don't know how I</p> <p>7 could be more specific.</p> <p>8 Q. Okay. It's your understanding that</p> <p>9 Mylan is not the manufacturer of DIGITEK?</p> <p>10 A. Mylan doesn't manufacture that</p> <p>11 product.</p> <p>12 Q. Mylan --</p> <p>13 A. I'm not using that as a formal term.</p> <p>14 I am saying that they do not manufacture that</p> <p>15 product.</p> <p>16 Q. They also -- Mylan is not the holder</p> <p>17 of the ANDA?</p> <p>18 A. That is my understanding, correct.</p> <p>19 THE VIDEOGRAPHER: We're off the</p> <p>20 record at 10:15.</p> <p>21 (Recess taken.)</p> <p>22 THE VIDEOGRAPHER: We are back on the</p> <p>23 record. The time is 10:19.</p> <p>24 BY MR. KAPLAN:</p> <p>25 Q. When I was asking you questions about</p>

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<p style="text-align: right;">Page 330</p> <p>1 the difference between NDA and ANDA and you said I 2 don't know, that's going beyond my area of 3 expertise. 4 A. Correct. 5 Q. You are not an expert in regulatory 6 affairs? 7 A. That is correct. 8 Q. FDA regulatory affairs? 9 A. That is absolutely correct. 10 Q. You don't hold yourself out to be an 11 expert? 12 A. That's correct. 13 Q. All right. Can you define -- you used 14 the term contract manufacturer? 15 A. Yes. 16 Q. What is a contract manufacturer? 17 A. It's -- it's a company that you have a 18 formal agreement with that manufactures product 19 to -- to some predetermined specification. 20 Q. Well, in -- in this case, you told me 21 that Actavis is the manufacturer of DIGITEK? 22 A. Correct. 23 Q. Actavis is the holder of the ANDA? 24 A. That's what I read. 25 Q. So Actavis manufactures DIGITEK in</p>	<p style="text-align: right;">Page 332</p> <p>1 MR. KAPLAN: Would you repeat that? 2 (Record read.) 3 MS. CARTER: Object to form. 4 A. If I understand the question, you're 5 asking there is an ANDA. And in that, it has 6 content that talks about the CMC section. It talks 7 about chemistry, manufacturing, and control. I as 8 part of my profession, I don't go into either an NDA 9 or an ANDA and look what the agreement has been 10 reached between -- between the company and the FDA. 11 So I don't -- I don't read that at all. I have no 12 interest in it whatsoever. 13 BY MR. KAPLAN: 14 Q. How does the FDA qualify a 15 manufacturer? 16 A. How do they qualify a manufacturer? 17 They do a preapproval. They -- they read whatever 18 the submission is, whether it's medical device with 19 PMA or 510K or an ANDA or an NDA. They then 20 schedule, in most instances, a preapproval 21 inspection. They would come in and they would 22 review your GMP, they would spend whatever time they 23 felt was appropriate, and then they would issue you 24 as -- as a part of that approval process, issue you 25 an approval letter.</p>
<p style="text-align: right;">Page 331</p> <p>1 accordance with the specifications set forth in the 2 ANDA; is that right? 3 A. I don't know. I haven't read the 4 ANDA. 5 Q. So your -- that is something that 6 you're just not familiar with? 7 A. It's something I wouldn't read because 8 it not within my expertise. 9 Q. Okay. Well, I'm just trying to set 10 some basic understandings here -- 11 A. Yes. 12 Q. -- or lack thereof. 13 A. Yeah. 14 Q. I mean, maybe -- maybe you don't 15 understand the -- the roles of the various companies 16 involved here. 17 A. Uh-huh. 18 Q. But I want to find out what you know 19 and what you don't know. So you don't know whether 20 Actavis as the holder of the ANDA for DIGITEK was 21 charged with the responsibility for manufacturing 22 DIGITEK in accordance with the specifications set 23 forth in the ANDA? 24 A. Sir, you're going to have to repeat 25 that. I'm sorry.</p>	<p style="text-align: right;">Page 333</p> <p>1 Q. In this case, in this situation with 2 regard to DIGITEK, Actavis was qualified by the FDA 3 as the manufacturer of that product, right? 4 A. I -- I don't know. I didn't see that 5 document. It was done apparently in the '90s 6 sometime. 7 Q. Who do you think was qualified as the 8 manufacturer of DIGITEK? 9 A. I don't know. 10 Q. You have no idea? 11 A. No, I didn't see the documents. 12 Q. Do you think it was Mylan? 13 A. I have no idea. 14 Q. Come on. You know that Mylan was not 15 the manufacturer, right? 16 A. I know they did not manufacture the 17 product. 18 Q. You know that Actavis did? 19 A. Correct. 20 Q. Is it fair to assume that if Actavis 21 was manufacturing DIGITEK, they were qualified to do 22 so by the FDA? 23 A. I would say it's fair to assume that 24 whatever FDA procedures were in place at the time of 25 approval that those procedures were followed.</p>

<p style="text-align: right;">Page 334</p> <p>1 Q. By Actavis?</p> <p>2 A. By the FDA in conjunction with</p> <p>3 Actavis.</p> <p>4 Q. But not Mylan?</p> <p>5 A. But not Mylan? I don't know what</p> <p>6 Mylan's role would be.</p> <p>7 Q. Well, you -- you told me it was your</p> <p>8 understanding that Mylan sold DIGITEK, right?</p> <p>9 A. Correct.</p> <p>10 Q. How is it that Mylan sold DIGITEK?</p> <p>11 A. Some type of agreement, verbal or</p> <p>12 written agreement, would have to be reached, and</p> <p>13 then they would sell the product. And I suppose</p> <p>14 there is -- there is some licenses that have to be</p> <p>15 obtained from the FDA, licenses which I'm not</p> <p>16 familiar with.</p> <p>17 Q. Well, tell me in this situation what</p> <p>18 you have seen that tells you how it is that DIGITEK</p> <p>19 came to be sold by Mylan.</p> <p>20 A. I -- I didn't go back that far in</p> <p>21 terms of reviewing that documentation.</p> <p>22 Q. What documentation are you talking</p> <p>23 about?</p> <p>24 A. I -- I didn't look at anything prior</p> <p>25 to '99, let's say.</p>	<p style="text-align: right;">Page 336</p> <p>1 documents you read to --</p> <p>2 A. Well, I don't recall the documents</p> <p>3 that I read, so that's not going to be possible.</p> <p>4 And my understanding is that Mylan had some -- an</p> <p>5 agreement with Actavis that they would be selling</p> <p>6 the product and that Actavis would be manufacturing</p> <p>7 that product.</p> <p>8 Q. Is that document that you were just</p> <p>9 talking about contained in the binder in front of</p> <p>10 you?</p> <p>11 A. Sir, I don't know what document it is,</p> <p>12 where I -- or I would have made that determination.</p> <p>13 Q. Who had the authority to confer upon</p> <p>14 Mylan the right and responsibility of manufacturing</p> <p>15 DIGITEK?</p> <p>16 A. You have to repeat that, sir.</p> <p>17 (Record read.)</p> <p>18 A. I don't know who had the right. I'm</p> <p>19 not -- I'm not sure I actually understand the</p> <p>20 question.</p> <p>21 Q. What don't you understand?</p> <p>22 A. I don't understand the question.</p> <p>23 Could you rephrase it, please.</p> <p>24 Q. Okay. Is it your understanding that</p> <p>25 it is the FDA and only the FDA that would have the</p>
<p style="text-align: right;">Page 335</p> <p>1 Q. So in all of your review of -- of --</p> <p>2 of documents in preparation for rendering your</p> <p>3 opinions which are contained in your report of</p> <p>4 June 15, 2010, and in preparation for your</p> <p>5 deposition on June 29 and again -- of 2010, and</p> <p>6 again today, February 16, 2011, you -- you reviewed</p> <p>7 no document that gave you any understanding of the</p> <p>8 relationship between Actavis and Mylan?</p> <p>9 A. No formal document that -- that's</p> <p>10 correct, no formal document. It would have been</p> <p>11 implied or stated to some extent in memos and the</p> <p>12 like.</p> <p>13 Q. But I'm going to ask the court</p> <p>14 reporter to repeat the question again, and I am</p> <p>15 going to ask you to answer it, please.</p> <p>16 A. Sure.</p> <p>17 Q. Yes or no. Yes, you did review any</p> <p>18 document or no, you didn't review?</p> <p>19 MR. KAPLAN: Would you repeat that?</p> <p>20 (Record read.)</p> <p>21 A. I read documents, yes, that did</p> <p>22 have -- gave me an understanding of the</p> <p>23 relationship.</p> <p>24 Q. I'm going to ask you what your</p> <p>25 understanding is of the relationship and what</p>	<p style="text-align: right;">Page 337</p> <p>1 authority to confer upon Mylan the right to</p> <p>2 manufacture DIGITEK?</p> <p>3 A. I don't know the process with Mylan</p> <p>4 that would give them the authority to be able to</p> <p>5 sell it. I was not involved with the regulatory</p> <p>6 affairs negotiations between the seller or the</p> <p>7 distributor of the product and the FDA.</p> <p>8 Q. That was not my question, and I'll ask</p> <p>9 the court reporter to read it back again. And</p> <p>10 concentrate on this, take your time.</p> <p>11 A. Yeah.</p> <p>12 MR. KAPLAN: Please read back the</p> <p>13 question.</p> <p>14 (Record read.)</p> <p>15 A. Oh, on Actavis? Oh, yes.</p> <p>16 Q. It's the FDA?</p> <p>17 A. That's correct.</p> <p>18 Q. Only the FDA?</p> <p>19 A. As far as I know -- well, I'm only</p> <p>20 involved with the FDA, but I know it is the FDA.</p> <p>21 Whether there are other legal groups, I don't know.</p> <p>22 Q. Mylan has no authority to authorize</p> <p>23 Actavis to manufacture DIGITEK?</p> <p>24 A. They don't have what?</p> <p>25 Q. Mylan has no authority to authorize</p>

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<p style="text-align: right;">Page 338</p> <p>1 Actavis to manufacture DIGITEK?</p> <p>2 A. Using the word "authorize," I believe</p> <p>3 that's correct.</p> <p>4 Q. Is there some other word that you</p> <p>5 would use?</p> <p>6 A. I don't know. Well, they would --</p> <p>7 they would establish an agreement, and as part of</p> <p>8 the agreement, to uphold the agreement, they would</p> <p>9 manufacture certain number of lots, certain</p> <p>10 quantity, under certain specifications, and other</p> <p>11 conditions, for Mylan. That I believe is the</p> <p>12 relationship that which I'm involved with in my --</p> <p>13 in my trade.</p> <p>14 Q. I don't know what you mean. Can you</p> <p>15 explain that, the relationship you're involved with</p> <p>16 in your trade?</p> <p>17 A. I'm involved -- the expertise that I</p> <p>18 bring is good manufacturing practices. Once an</p> <p>19 agreement is reached, a verbal agreement is reached</p> <p>20 between the two parties, I would look at the</p> <p>21 relationships of the supply and determine whether</p> <p>22 between the two parties my company, which would be</p> <p>23 the equivalent of Mylan, and the contract</p> <p>24 manufacturer, and I would determine whether or not</p> <p>25 the GMP conditions are adequately defined and</p>	<p style="text-align: right;">Page 340</p> <p>1 Q. And you referred to Actavis as a</p> <p>2 contract manufacturer, that's -- that's a term of</p> <p>3 art. What does that mean?</p> <p>4 A. It means a company that's making</p> <p>5 product for you, making -- manufacturing product for</p> <p>6 you.</p> <p>7 Q. And your understanding then is that --</p> <p>8 that Actavis was a contract manufacturer?</p> <p>9 A. That's a term that is used in the</p> <p>10 industry, yes.</p> <p>11 Q. What -- is that pursuant to</p> <p>12 regulation, contract manufacturer?</p> <p>13 A. Well, the FDA does use that term in</p> <p>14 some of its documents, so I would say it's an</p> <p>15 industry -- external manufacturer or contract</p> <p>16 manufacturer are the most common terms.</p> <p>17 Q. Is there a difference between a</p> <p>18 manufacturer that is the holder of an ANDA and a</p> <p>19 contract manufacturer?</p> <p>20 A. It's -- I -- from what I would say the</p> <p>21 Mylan standpoint based upon my experience as a Mylan</p> <p>22 perspective, there is no difference.</p> <p>23 Q. That wasn't my question.</p> <p>24 A. In terms of GMP.</p> <p>25 Q. That wasn't my question.</p>
<p style="text-align: right;">Page 339</p> <p>1 whether adequately executed.</p> <p>2 Q. Have you seen any such agreement?</p> <p>3 A. I have not seen a -- I saw a draft of</p> <p>4 a quality agreement which was not approved.</p> <p>5 Q. You have seen no other agreement</p> <p>6 between Actavis and Mylan?</p> <p>7 A. There was a supply agreement. I have</p> <p>8 not read the supply agreement.</p> <p>9 Q. Why not?</p> <p>10 A. Well, I didn't see it in the records.</p> <p>11 Q. Did you ask for it?</p> <p>12 A. I did not ask for it.</p> <p>13 Q. So in all of the work you've done, all</p> <p>14 hours that you've billed, all of the time that</p> <p>15 you've spent preparing for your report and writing</p> <p>16 your report and giving your deposition, preparing</p> <p>17 for your deposition, both on June 29, 2010 and again</p> <p>18 today on February 16, 2011, you've never asked for</p> <p>19 any supply agreement between Mylan and Actavis,</p> <p>20 correct?</p> <p>21 A. I don't recall asking specifically for</p> <p>22 a supply agreement.</p> <p>23 Q. So the answer to my question is no, I</p> <p>24 have not?</p> <p>25 A. No, I have not.</p>	<p style="text-align: right;">Page 341</p> <p>1 A. Okay.</p> <p>2 Q. I'm going to ask the court reporter to</p> <p>3 read back my question and see if you can try to</p> <p>4 answer specifically what I asked you.</p> <p>5 (Record read.)</p> <p>6 A. I am not aware of any difference from</p> <p>7 a Mylan perspective, from a GMP perspective.</p> <p>8 Q. Could you be more specific?</p> <p>9 A. That the GMP is all of the controls</p> <p>10 that are necessary -- if I'm the seller of a</p> <p>11 product, I am -- if I'm a distributor of a product,</p> <p>12 I sell it, I market it. I have a responsibility to</p> <p>13 all of those involved with it, the customers, the</p> <p>14 patients, et cetera. I have a responsibility -- and</p> <p>15 to the FDA, to make sure that GMPs are upheld both</p> <p>16 by my company and by the company manufacturing. So</p> <p>17 that the same level of controls in terms of GMP are</p> <p>18 in effect between the two parties, that they</p> <p>19 compliment one another to meet the GMP requirements.</p> <p>20 Q. So are you saying that according to</p> <p>21 the code of federal regulations which the GMPs are</p> <p>22 contained?</p> <p>23 A. Correct.</p> <p>24 Q. That Mylan as the seller of DIGITEK</p> <p>25 had responsibility under the law to make sure that</p>

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<p style="text-align: right;">Page 342</p> <p>1 GMPs were upheld in the manufacture of DIGITEK?</p> <p>2 A. That is correct.</p> <p>3 Q. And can you -- can you cite me to</p> <p>4 that -- to that -- those regulations that put that</p> <p>5 responsibility on a seller?</p> <p>6 A. I cannot right this second.</p> <p>7 Q. Well, take your time.</p> <p>8 A. Well, I don't have it here, but I</p> <p>9 believe there is. I cannot cite it currently, but I</p> <p>10 believe there's enough information in print that</p> <p>11 says that if I am Mylan, I am responsible for</p> <p>12 ensuring that product manufactured in my name for me</p> <p>13 has to meet GMP requirements.</p> <p>14 Q. Okay. And I'm just asking you to tell</p> <p>15 me, show me what it is that you have reviewed, seen,</p> <p>16 relied upon in arriving at your opinions in this</p> <p>17 case that leads you to believe that a seller of a</p> <p>18 product has the responsibility to make sure that the</p> <p>19 manufacturer of the product who is the ANDA holder</p> <p>20 complies with GMPs?</p> <p>21 A. I can tell you through my experience</p> <p>22 that I've been trained to -- to -- to ensure -- to</p> <p>23 establish a relationship with the contract</p> <p>24 manufacturer and that ensuring that I as -- Mylan,</p> <p>25 if you will -- and the contractor have a full</p>	<p style="text-align: right;">Page 344</p> <p>1 A. I cannot point to a document.</p> <p>2 Q. You can't point to a document in</p> <p>3 your -- referenced in your report, can you?</p> <p>4 A. That is correct.</p> <p>5 Q. You can't point to a document, any</p> <p>6 document that you brought here today, can you?</p> <p>7 A. I -- I don't know. I'd have to -- at</p> <p>8 this particular point, I can't point to a document.</p> <p>9 I'd have to think about it and do a little more</p> <p>10 research in order to confirm what I know.</p> <p>11 Q. With all due respect, I asked you if</p> <p>12 you came here today prepared to give your opinions</p> <p>13 and you said yes.</p> <p>14 A. I was prepared.</p> <p>15 Q. You are prepared, aren't you.</p> <p>16 A. I am prepared. But you're asking me a</p> <p>17 question that I cannot answer at this particular</p> <p>18 point.</p> <p>19 Q. Pretty fundamental to your opinions as</p> <p>20 to Mylan, isn't it?</p> <p>21 A. If that's -- I would not say that, no.</p> <p>22 I don't think it's fundamental to our discussions.</p> <p>23 Q. You don't think that the legal</p> <p>24 requirements for ensuring compliance with GMPs is</p> <p>25 fundamental to your opinions as to Mylan?</p>
<p style="text-align: right;">Page 343</p> <p>1 compliment and meet the GMP requirements that I am</p> <p>2 responsible and accountable for them.</p> <p>3 Q. I'm going to move to strike that as</p> <p>4 nonresponsive and ask the court reporter to read</p> <p>5 back my question. And ask you to answer the</p> <p>6 question that I asked you.</p> <p>7 A. Okay.</p> <p>8 (Record read.)</p> <p>9 A. I cannot show you right this second</p> <p>10 what it is. It's just that is my understanding</p> <p>11 based upon years of experience and reading documents</p> <p>12 and warning letters and GMPs and preambles and</p> <p>13 guidance documents, I would say that is my</p> <p>14 understanding. So I cannot -- if you want to</p> <p>15 restate the question.</p> <p>16 Q. You cannot?</p> <p>17 A. I don't know. Restate the question.</p> <p>18 I want to make sure I answer it.</p> <p>19 Q. There is no document --</p> <p>20 A. That I can point to.</p> <p>21 Q. That you can point to. There is no</p> <p>22 document upon which you rely to conclude that Mylan</p> <p>23 as the seller of DIGITEK had the responsibility for</p> <p>24 ensuring that Actavis as the ANDA holder and</p> <p>25 manufacturer of DIGITEK complied with GMPs?</p>	<p style="text-align: right;">Page 345</p> <p>1 A. I am saying that I am aware of what</p> <p>2 are industry norms, what are standards, between a</p> <p>3 contracting company and a contract manufacturer, but</p> <p>4 I cannot pinpoint a document right this second which</p> <p>5 establishes that in terms of law.</p> <p>6 Q. The legal responsibility for complying</p> <p>7 with GMPs is fundamental to any opinion you are</p> <p>8 offering in this case, isn't it?</p> <p>9 MS. CARTER: Object to form.</p> <p>10 A. Yes.</p> <p>11 BY MR. KAPLAN:</p> <p>12 Q. And you keep referring to Actavis as a</p> <p>13 contract manufacturer.</p> <p>14 A. The relationship that Mylan has, if</p> <p>15 I'm looking at it from Mylan's perspective, they are</p> <p>16 what's referred to as a contract manufacturer. And</p> <p>17 Mylan refers to them as a contract manufacturer.</p> <p>18 Q. What's the basis for concluding that</p> <p>19 Actavis is a "contract manufacturer"?</p> <p>20 A. It's in various documents where they</p> <p>21 talk -- talk to Actavis as the contract</p> <p>22 manufacturer.</p> <p>23 Q. How does a contract manufacturer</p> <p>24 differ from a manufacturer who has an approved ANDA</p> <p>25 approved by the FDA? What is the difference?</p>

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Mark Kenny, Volume II

Videotaped

February 16, 2011

<p style="text-align: right;">Page 346</p> <p>1 A. I don't see any difference. From 2 Mylan's perspective. 3 Q. Well, from your perspective? 4 A. But my perspective is in terms of my 5 experience, I've never been a contract manufacturer. 6 My perspective is as the company that distributes 7 the product that I am obligated, I've been trained 8 to assume that obligation that I have to be in 9 compliance with GMP, and that the company that makes 10 the product for us has to be compliant to GMP. 11 Q. When you say I have to be compliant 12 with GMP, what do you mean? 13 A. I means -- some people refer to the 14 distributor as a virtual company. As part of a 15 virtual company, you'll have systems and procedures, 16 you'll have specifications that you approve. You 17 will have other procedures that are approved. You 18 perhaps have complete handling responsibility. And 19 those would be -- there are supposed to be 20 established between you and the contractor as to 21 what my obligations were to compliment the FDA's 22 requirements and what your obligations are to meet 23 FDA requirements. 24 Q. You started by saying some people 25 refer to a distributor as a virtual company. When</p>	<p style="text-align: right;">Page 348</p> <p>1 regulation. 2 Q. But it's your understanding that the 3 FDA requires a seller of a product, in this case 4 Mylan, to approve manufacturing specifications for 5 the manufacture of DIGITEK by Actavis? 6 A. To approve product specifications. 7 Q. What's the difference between 8 manufacturing specifications and product 9 specifications? 10 A. Product specifications are an end 11 specification. Manufacturing is how you make it. 12 Q. Be a little more specific. 13 A. Manufacturing would be the process of 14 putting two chemicals together to -- and et cetera, 15 to process it to become a finished product. And at 16 that particular point, as a finished product, you 17 would have a product specification. 18 Q. You're saying that the responsibility 19 for the product specifications with regard to 20 DIGITEK rests with Mylan? 21 A. A portion of that, most certainly. 22 Q. What portion? 23 A. They need to have approved 24 specifications in their system as to what they are 25 buying. You have to know what you're buying. What</p>
<p style="text-align: right;">Page 347</p> <p>1 you say "some people," who are you talking about? 2 A. In the industry, it's a common term. 3 Q. Who is the industry? 4 A. The industry are my peers. 5 Q. I don't know who your peers are. 6 A. My peers are companies that I have 7 either worked for or have some relationship with. 8 It's -- I would call it it's an informal term that 9 is used. 10 Q. Is the FDA -- 11 A. No, the FDA does not use that term, 12 that I've ever seen. 13 Q. So the FDA that has established good 14 manufacturing practice regulations does not use the 15 term "virtual company"? 16 A. As far as I know. I don't know if 17 they use that term. I've never seen it used by 18 them. 19 Q. And you said that a seller of a 20 product has to approve specifications -- 21 A. That's correct. 22 Q. -- for a product? Can you -- can you 23 cite me to the -- to the regulations that impose 24 that responsibility on the seller? 25 A. Sir, if I -- I cannot cite you to the</p>	<p style="text-align: right;">Page 349</p> <p>1 am I buying? I define it as a specification of 2 which Mylan or -- sorry -- Actavis, in this case, or 3 the contractor, would manufacture in accordance to. 4 So they deliver a product that meets my 5 specification. I take ownership for it because it's 6 my product, it is my specification. 7 Q. So it's your understanding that -- 8 that Mylan tells Actavis what the specifications for 9 DIGITEK are to be? 10 A. No, I didn't say that. I said that I 11 don't know who tells who. All I can tell you is 12 that Mylan would have an approved specification that 13 they would use to determine whether or not the 14 product met their own specification and was fit to 15 be distributed. 16 Q. Let's go back. Isn't it the FDA that 17 has to approve the specifications for the 18 manufacturer of DIGITEK? 19 A. No. 20 Q. No? 21 A. Not the specifications. They would -- 22 I wouldn't use that term. You asked me 23 specifications, I would say no. 24 Q. So it's not the FDA that has to 25 approve the specifications for the manufacture of</p>

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<p style="text-align: right;">Page 350</p> <p>1 DIGITEK?</p> <p>2 A. The FDA does approve certain</p> <p>3 information that's required by -- by them. That is</p> <p>4 contained in an ANDA and an NDA, and the product has</p> <p>5 to be manufactured according to those requirements.</p> <p>6 Q. Well, what -- what authority does</p> <p>7 Mylan have with regard to product specifications?</p> <p>8 A. I don't know. If I understand your</p> <p>9 question, I would say -- could you repeat the</p> <p>10 question? I don't think I'm answering the right</p> <p>11 question.</p> <p>12 (Record read.)</p> <p>13 A. Mylan has an obligation to have</p> <p>14 product specifications that they use to determine</p> <p>15 the acceptability of a product to be distributed in</p> <p>16 their name.</p> <p>17 Q. I'm going ask you the question again.</p> <p>18 I'll just repeat it. What authority does Mylan have</p> <p>19 under the law with respect to product specifications</p> <p>20 for DIGITEK?</p> <p>21 A. I don't know. Under the law.</p> <p>22 Q. Well, we were going through the</p> <p>23 notebook you brought of all of the Mylan documents</p> <p>24 that you have looked at since your deposition was</p> <p>25 taken initially on June 29, 2010?</p>	<p style="text-align: right;">Page 352</p> <p>1 The portion you've highlighted starts with</p> <p>2 "Actavis's U.S. head of quality would be calling."</p> <p>3 Then, "Mike Adams and I spoke to her on the phone,</p> <p>4 and she described that the PAI had been going on for</p> <p>5 six weeks and that they were being "beaten up" by</p> <p>6 FDA. She stated that the reason the recall was</p> <p>7 expanded to all DIGITEK was that FDA felt that there</p> <p>8 weren't adequate controls on their tablet presses to</p> <p>9 ensure that the double tablet issue couldn't have</p> <p>10 happened previously." Then you -- then you</p> <p>11 highlighted a portion of a sentence that says that</p> <p>12 "other products were being recalled."</p> <p>13 And then on the second page of M25,</p> <p>14 you've highlighted "FDA is focusing on Amide's</p> <p>15 systems to control and ensure product quality rather</p> <p>16 than simply having concerns over just one</p> <p>17 investigation." And then finally, you highlighted</p> <p>18 the following: "Mike Adam, Cass, C-A-S-S, Bird, and</p> <p>19 Ann Wolf, who've lead the charge from the MPI side."</p> <p>20 So tell me what you learned or what was</p> <p>21 the significance there.</p> <p>22 A. Well, there is only one sentence, if</p> <p>23 you will, that I would say is -- was meaningful for</p> <p>24 me. And she stated -- it says, "she stated the</p> <p>25 reason the recall was expanded to all DIGITEK was</p>
<p style="text-align: right;">Page 351</p> <p>1 A. Right.</p> <p>2 Q. We've actually only gotten through two</p> <p>3 documents. There was an exhibit M55 and an exhibit</p> <p>4 M53. Tell me what the next document is.</p> <p>5 So the next document you're handing me is</p> <p>6 marked Exhibit M21, and it is a e-mail from a John</p> <p>7 Deiriggi, D-E-I-R-I-G-G-I, to Hal Korman,</p> <p>8 K-O-R-M-A-N, dated January 4, 2007. And then an</p> <p>9 e-mail below that from Walt Owens to John Deiriggi</p> <p>10 dated January 4, 2007. There's nothing that you've</p> <p>11 highlighted here.</p> <p>12 A. There was nothing of interest in</p> <p>13 there.</p> <p>14 Q. All right. So M21, nothing of</p> <p>15 interest, right?</p> <p>16 A. Correct.</p> <p>17 Q. The next Mylan document that you</p> <p>18 reviewed.</p> <p>19 A. Here's another one.</p> <p>20 Q. Okay. The next document you've handed</p> <p>21 me is another exhibit from a previous deposition,</p> <p>22 and it's marked Exhibit M25. It's an e-mail from</p> <p>23 Chuck Koons to Hal Korman dated April 27, 2008. And</p> <p>24 you have highlighted a portion on the first and</p> <p>25 second page, I'll just refresh your recollection.</p>	<p style="text-align: right;">Page 353</p> <p>1 that FDA felt there weren't adequate controls on</p> <p>2 their tablets -- tablet press, to ensure that double</p> <p>3 thick issues couldn't have happened previously."</p> <p>4 That was the -- to me the notable sentence.</p> <p>5 Q. Okay. And by the way, these documents</p> <p>6 that you've just gone through, you hadn't reviewed</p> <p>7 those prior to rendering your opinions in this case?</p> <p>8 A. No, I -- I almost assuredly did see</p> <p>9 them. M25, I did.</p> <p>10 Q. Okay. And if they were significant to</p> <p>11 you, you would have referenced them in your report?</p> <p>12 A. If they were significant -- if I felt</p> <p>13 they were significant at the time, I would have</p> <p>14 referenced them in my report.</p> <p>15 Q. Because all of your opinions are</p> <p>16 contained within the four corners of your report?</p> <p>17 A. That is correct. That is correct.</p> <p>18 Q. And you understand that that is your</p> <p>19 obligation here?</p> <p>20 A. You've asked me that and I will repeat</p> <p>21 it and say I understand that.</p> <p>22 Q. I just want to make sure we're on the</p> <p>23 same wave length.</p> <p>24 A. We're on the same wave length</p> <p>25 100 percent.</p>

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<p style="text-align: right;">Page 354</p> <p>1 Q. Thanks. And reference was made to 2 Amide, A-M-I-D-E. You understand that when 3 reference was made to Amide, that's Actavis? 4 A. That is correct. That's my 5 understanding. 6 Q. Okay. And you also understand that 7 throughout the documents, when reference is made to 8 Bertek, B-E-R-T-E-K, that means Mylan? 9 A. That's correct. That's my 10 understanding. 11 Q. All right. The next document that you 12 reviewed since your deposition was taken initially 13 on June 29, 2010. 14 A. Reviewed or rereviewed? 15 Q. You can tell me whether you reviewed 16 or rereviewed. 17 A. Well, I reread. I reread Adams. 18 There was nothing -- 19 Q. You reread what? 20 A. I'm sorry. Let me tell you what I 21 reread. The deposition taken on Michael Adams 22 January 22, 2010, I think that's it. And I reread 23 it to just familiarize myself. They are long 24 documents, hundreds of pages. 25 Q. When you say you reread the deposition</p>	<p style="text-align: right;">Page 356</p> <p>1 Q. After June 29, 2010? 2 A. That is correct. 3 Q. And what did you learn from that? 4 A. Nothing. 5 Q. Did you look at any other Mylan 6 deposition? 7 A. I looked at Chuck Koons. 8 Q. Again? 9 A. Yes. 10 Q. What did you learn from that? 11 A. I learned that Mr. Koons had not a 12 good memory. 13 Q. Well, I'm going to move to strike that 14 as nonresponsive. 15 A. Nothing that I recall notable. 16 Q. How is your memory? 17 A. Mediocre to good. Depends. Sometimes 18 it's very, very good. 19 Q. How is it today? 20 A. I believe it's pretty good. 21 Q. Okay. All right. Any other Mylan 22 depositions that you reviewed? 23 A. No, that's it. If it's here, then I 24 reviewed it. 25 Q. So Mike Adams and Chuck Koons, and</p>
<p style="text-align: right;">Page 355</p> <p>1 of Mike Adams, don't you recall that at your 2 previous deposition when you were asked whether you 3 reviewed any Mylan depositions, you said the only 4 one you looked at was Chuck Koons? 5 A. I -- I read documents where I quickly 6 went through them, and perhaps I was in error. I 7 think I did read Michael Adams because I did see 8 certain phrases where -- they were interesting 9 phrases. They were at least mentally notable to me. 10 Q. So you think that when you -- when you 11 testified on June 29, 2010 that the only Mylan 12 deposition you reviewed was Chuck Koons, you were 13 wrong? 14 A. I believe I was wrong, correct. 15 Q. And you think you also had reviewed 16 Mike Adams' deposition? 17 A. I'm sorry, I think I got these 18 backwards. Could you repeat your question? 19 Q. You think that before your June 29 20 deposition was taken, you had also reviewed Mike 21 Adams' deposition? 22 A. I believe I did, yes. 23 Q. And then you re-reviewed Mike Adams' 24 deposition? 25 A. Correct.</p>	<p style="text-align: right;">Page 357</p> <p>1 there's nothing remarkable that you gleaned from 2 either of those depositions? 3 A. No. 4 Q. All right. What is the next document 5 that you reviewed? Since June 29, 2010? 6 A. I could short -- well, I'll go through 7 it per your process. 8 Q. If you want to shortcut it, I'm all in 9 favor of it. Tell me how you can shortcut it. 10 A. Well, let's go through it so I don't 11 misspeak. 12 Q. I don't want you to misspeak. 13 A. Okay. I read this particular 14 document, you can look at it. And I made no -- 15 there was nothing remarkable in there. 16 Q. Okay. So what you're handing me is a 17 document marked Exhibit M65, which bears a Bates 18 stamp -- which bears Bates stamp numbers UD as in 19 dog, LL 000005805 through 5818. 20 (Cell phone interruption.) 21 Q. Does your handwriting appear anywhere 22 on here? 23 A. Yes. 24 Q. Is it on the front page? 25 A. Yes, it is.</p>

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<p style="text-align: right;">Page 358</p> <p>1 Q. And if I can read this correctly, it 2 says receiving and then there's an arrow, four of 3 96, 00S thickness found at UDL PKG 70175A. What 4 does that mean? 5 A. It's -- it's just when I looked 6 through it, there was an out of specification when I 7 review documents as any GMP person does, he or she 8 would look for the term out of specification, 9 because it's potentially notable when I reviewed it. 10 It was meaningless in the context to my expert 11 opinion. 12 Q. Who is UDL? 13 A. UDL is apparently a contract packaging 14 firm that I believe there's probably a Mylan 15 relationship with. 16 Q. What do they do? 17 A. They -- I think they form blister 18 packs, at least I read that. 19 Q. Blister packs of? 20 A. Of I would guess Digoxin, and perhaps 21 others, I don't know, but it was not important to 22 me. Okay? 23 Q. So there is nothing important to you 24 about document M65 that has anything to do with any 25 opinion that you're rendering in this case?</p>	<p style="text-align: right;">Page 360</p> <p>1 (Whereupon, Rick Fern joined the 2 deposition.) 3 THE VIDEOGRAPHER: We're back on the 4 record. The time is 11:18. This is the 5 beginning of tape two. 6 BY MR. KAPLAN: 7 Q. Okay. Mr. Kenny, I think we had just 8 talked about Exhibit M65, which you told me was one 9 of the Mylan documents that you reviewed since your 10 deposition was taken on June 29, 2010, and that 11 there was nothing remarkable about that document, 12 correct? 13 A. That is correct. 14 Q. All right. Moving on. Let's go to 15 the next Mylan document in your notebook, please. 16 A. (Handing). 17 Q. You're handing me a document which was 18 previously marked as deposition Exhibit M47 bearing 19 the Bates numbers UDLL 000211178 through 182. Looks 20 like an e-mail string that ends up with an e-mail 21 from Lee Radtke to Val Schissel, S-C-H-I-S-S-E-L, 22 dated Friday December 14, 2007. I see no 23 highlighting -- 24 A. Right. 25 Q. -- of yours on this document?</p>
<p style="text-align: right;">Page 359</p> <p>1 A. Not in the least bit. 2 Q. Okay. Thank you. Okay. The next 3 Mylan document that you reviewed. 4 Okay. You've handed me a document that 5 is Exhibit M52 which bears the Bates stamp numbers 6 UDLL 0000014256 through 14268. UDL document you've 7 highlighted that it's from Lee Radtke dated 8 February 10, 2007, re 483/warning letter summary for 9 Actavis (Amide.) And I see no other highlights 10 throughout the document. 11 A. It was not remarkable. 12 Q. There was nothing remarkable about 13 Exhibit M52. 14 A. Correct. 15 Q. It had no bearing on your opinion in 16 any way, shape, or form; is that right? 17 A. Zero. That is correct. 18 Q. Zero, zero, zippo. It's 11 o'clock. 19 You want to take a break? 20 A. No. 21 Q. You don't? I do. 22 THE VIDEOGRAPHER: We're off the 23 record. The time is 11:02. This is the end 24 of tape 1. 25 (Recess taken).</p>	<p style="text-align: right;">Page 361</p> <p>1 A. Nothing remarkable. 2 Q. And -- and you're concluding and 3 telling me that there is nothing remarkable that you 4 found in your review or rereview of previously 5 marked Exhibit M47, correct? 6 A. That is correct. 7 Q. Thank you, sir. 8 A. (Handing). 9 Q. Okay, sir. The next Mylan document 10 that you reviewed or rereviewed which you've just 11 handed me is one that was previously marked Exhibit 12 M45 bearing the number UDLL 000025489 through, looks 13 like we don't have a consecutively numbered exhibit 14 here. The first two pages are -- and it's last four 15 digits are 5489 and 5490, and then attached to that 16 is a document headed "UDL Laboratories, Inc. Quality 17 Assurance (in process)" with Bates numbers MYLN 18 000035615 through 35620. And actually it's -- that 19 document as I flip through it is out of order, 20 because I think it starts actually with 35607 and 21 continues through 35620. Anyway, tell me, I see it 22 looks like -- I'm starting to recognize your 23 handwriting here, you circled the date January 21, 24 2008, and you have written "still no Q agreement"? 25 A. It's -- it's meaningless comment. It</p>

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<p style="text-align: right;">Page 362</p> <p>1 had -- nothing remarkable there. I'd have to go 2 through it to even tell you why I put that down. 3 Q. Okay. Is there anything at all 4 remarkable about this document or anything -- 5 A. Not in the least bit. 6 Q. Thank you. And it -- it had no 7 influence whatsoever on your opinions? 8 A. Zero. 9 Q. By the way, we talked about UDL 10 before. In all of your preparation for your report 11 which you submitted on June 15, 2010, and in 12 preparation for your deposition on June 29, 2010 and 13 again here today on February 16, 2011, have you seen 14 anything that would indicate to you that at any time 15 that UDL tested DIGITEK tablets to make sure that 16 they were in accordance with -- 17 A. I saw some -- I saw some test 18 information. I saw no exceptions. I saw no out of 19 specification test results. 20 Q. Next document. 21 A. (Hanging). 22 Q. This is a previously marked deposition 23 exhibit M39 bearing Bates stamp numbers MYLN 24 0000000381 through 385, and it looks like somebody's 25 handwriting on all of the -- all of the pages here.</p>	<p style="text-align: right;">Page 364</p> <p>1 you -- you had reviewed, right? 2 A. That's correct. 3 Q. And it is an e-mail from Mr. Adams to 4 a Mr. Elinski, E-L-I-N-S-K-I, dated May 13, 2008, 5 Bates numbers MYLN 000035283 through 35285. 6 Anything at all remarkable about that document? 7 A. Nothing, zero. 8 Q. Nothing that enlightened you in any 9 way? 10 A. Not in any way. 11 Q. Nothing that affected any opinion that 12 you have rendered in this case? 13 A. That is correct. (Hanging.) 14 Q. The next document that you've handed 15 me that you reviewed or rereviewed since your 16 deposition was taken on June 29, 2010 is marked -- 17 was previously marked as deposition Exhibit M30, 18 again, from the deposition of Mr. Adams, and it's an 19 e-mail from Mr. Adams to a number of people dated 20 May 6, 2008. Is there anything about that document 21 that you found remarkable? 22 A. Nothing remarkable. 23 Q. Enlightening? 24 A. Not in the least bit. 25 Q. So there is nothing about Exhibit M30</p>
<p style="text-align: right;">Page 363</p> <p>1 What does this mean to you? 2 A. Nothing. There is nothing remarkable. 3 Q. Nothing remarkable and nothing about 4 previously marked Exhibit M39 which had any bearing 5 whatsoever on -- on any opinion that you rendered in 6 this case? 7 A. That is correct. 8 Q. Thank you. 9 A. (Hanging). 10 Q. All right. The next document that you 11 handed me that you have either reviewed or 12 rereviewed since your deposition was first taken on 13 June 29, 2010 is a previously marked deposition 14 exhibit M-34 with Bates number MYLN 000000408, a 15 one-page document headed "recall team." Anything 16 remarkable about that document? 17 A. Not in the least bit. 18 Q. So nothing about Exhibit M34 that has 19 had any bearing on any opinion that you've rendered 20 in this case? 21 A. That is correct. (Hanging). 22 Q. The next document you're handing me is 23 a previously marked deposition Exhibit M31. It 24 looks like it was marked in the deposition of 25 Mr. Adams, the deposition that you just told me that</p>	<p style="text-align: right;">Page 365</p> <p>1 that in any way bears upon the facts or your opinion 2 in this case? 3 A. That is correct. There is -- correct. 4 (Hanging). 5 Q. By the way -- and you just handed me 6 another document, and I'm going to go into that, but 7 I just want to make sure I understand this on your 8 educational background. You have a undergraduate 9 degree in engineering? 10 A. That's correct. 11 Q. What -- what specialization? 12 A. Mechanical engineering. 13 Q. And that's from what school? 14 A. University of Dayton. 15 Q. University of Dayton. Dayton, Ohio? 16 A. That's correct. 17 Q. So a guy from New Jersey goes out to 18 Ohio for school, right? 19 A. That's correct. 20 Q. All right. The Dayton fliers? 21 A. You got it. 22 Q. All right. You have no graduate 23 degree? 24 A. I do not have a graduate degree, 25 that's correct.</p>

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<p style="text-align: right;">Page 366</p> <p>1 Q. Okay. You've just handed me what has 2 been previously marked as deposition Exhibit M26, 3 again, from the deposition of Mr. Adams that you 4 told me today that you reviewed but found nothing 5 remarkable in it. Here, I see your handwriting, I 6 think it says by Mr. Adams' name, executive director 7 QA at Mylan? 8 A. Yes. 9 Q. Okay. Anything about M26 that you 10 found remarkable? 11 A. Nothing remarkable. 12 Q. Or enlightening? 13 A. It did not enlighten any further. 14 Q. Or that bears in any way on any 15 opinion that you have rendered in this case? 16 A. It does not bear on any opinion. 17 (Handing). 18 Q. The good new is for the record, it 19 looks like we're getting closer to the end here. 20 A. Yeah, well, you asked for this. 21 Q. I did, I did. Well, I you didn't ask 22 for it. You just -- I did ask for it. You have 23 handed me what has been previously marked as 24 deposition Exhibit M54 with Bates numbers MYLN 25 000997539 and 7540. A document dated December 13,</p>	<p style="text-align: right;">Page 368</p> <p>1 It appears to have established some type of legal 2 agreement, but since I'm not familiar with the 3 terms, it has no bearing whatsoever. 4 Q. Okay. And -- and this document on 5 Page 32343 refers to a written supply and 6 distribution agreement covering DIGITEK. Have you 7 seen that? 8 A. Yes, I have, sir. 9 Q. And anything about that agreement that 10 you found important? 11 A. The -- it's the lack of information 12 that I found important. It did not have the clauses 13 in it and the requirements, and it didn't establish 14 the GMP responsibilities between two parties. 15 Q. It did not establish the GMP 16 responsibilities between the two parties? 17 A. Right. It didn't deal -- 18 Q. Go ahead. 19 A. It didn't deal in the specifics that 20 are required to run a business. 21 Q. Okay. What are the specifics required 22 under the law to "run a business," as you put it? 23 A. Well, you -- if -- can I pull the GMP? 24 Q. Can you pull what? 25 A. The good manufacturing practices to</p>
<p style="text-align: right;">Page 367</p> <p>1 2006 from Lee Radtke to Chuck Koons. I'll ask you 2 the same question, is there anything that you found 3 remarkable about that document? 4 A. Nothing remarkable. 5 Q. Or enlightening? 6 A. It did not enlighten me at all. 7 Q. So it had no bearing on any opinion 8 that you've given in this case? 9 A. That is correct. 10 Q. The next document that you've handed 11 me that you've reviewed or rereviewed since your 12 deposition was taken on June 29, 2010 is a two-page 13 document bearing Bates numbers MLYN 000032342 and 14 32343. It looks like a letter dated November 23, 15 2006 to Actavis from Christopher Benson, director of 16 technical purchasing at Mylan Pharmaceuticals, Inc., 17 with an attachment regarding the fact that "Mylan is 18 an authorized distributor of record and has an 19 ongoing relationship with Actavis pursuant to a 20 written supply and distribution agreement covering 21 DIGITEK .125 milligrams and .25 milligrams." Is 22 that right? 23 A. That is correct. 24 Q. Anything remarkable about that? 25 A. No. I did not read that beforehand.</p>	<p style="text-align: right;">Page 369</p> <p>1 show you what I believe can help answer that? 2 Q. Well, just answer my question. 3 A. That's the way I would answer that. 4 I'd like to read that. 5 Q. You would like to read a GMP -- 6 A. Just one clause within the GMP. 7 Q. When you say "the GMP," there are a 8 lot of GMPs, aren't there? 9 A. Yeah. This is -- this is part 210 and 10 part 211. It's specifically in part 211 -- CFR part 11 211. 12 Q. Sounds like you're pretty familiar 13 with that? 14 A. I'm reasonably familiar with that. 15 Q. CFR 211? 16 A. Right. Well, I'd have to go to the 17 particular clause. 18 Q. Okay. By the way, was the supply and 19 distribution agreement a document that you reviewed 20 before your deposition was taken? 21 A. Yes, it was. I have not reviewed it 22 since. 23 Q. Was it a document that you reviewed 24 before you issued your report in this case? 25 A. Yes, it was.</p>

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<p style="text-align: right;">Page 370</p> <p>1 Q. Is it a document that you have 2 referenced in your report? 3 A. I have not referenced it. 4 Q. Why not? 5 A. Because it was remarkable by its 6 absence of information. Supply agreements in -- in 7 my experience do not contain any information that is 8 associated with the details of good manufacturing 9 practices. Therefore, when I see a supply agreement 10 and I flip through it and it has nothing, no 11 attachments, no references, it's -- it's of no 12 interest to me. 13 Q. So what -- what I'm interested in and 14 what I'm going to ask you to go ahead and -- and 15 show me then is the CFR, the code of federal 16 regulations, dealing with good manufacturing 17 practices which requires Mylan to have included 18 something that you say was missing from the supply 19 and distribution agreement. 20 A. Okay. 21 Q. In its status as the distributor of 22 DIGITEK manufactured by Actavis pursuant to its 23 abbreviated new drug application approved by the 24 FDA? 25 A. I understand.</p>	<p style="text-align: right;">Page 372</p> <p>1 the documents that you referenced in -- in arriving 2 at your opinions, right? 3 A. That is correct. 4 Q. The significant documents, right? 5 A. That is correct. 6 Q. And there are -- there are 60 of them; 7 is that right? 8 A. There are -- whatever that number is, 9 yeah. 10 Q. I'm looking at page 42, and the last 11 document listed is number 60? 12 A. Then that's it. That's correct. 13 Q. It's a two-page document, appendix B, 14 as in boy, references pages 41 and 42 of your 15 report, lists documents one through 60, right? 16 A. That's correct. 17 Q. Okay. You're handing me -- you're 18 handing me 21 CFR section 211.22 entitled, 19 "Responsibilities of Quality Control Unit; is that 20 right? 21 A. That is correct. 22 Q. Who is that directed to? 23 A. That's directed to the distributor and 24 the manufacturer. 25 Q. Where -- where do you see that it's --</p>
<p style="text-align: right;">Page 371</p> <p>1 Q. Okay. Do you understand? 2 A. I believe so. 3 Q. All right. Show me what you've got. 4 Okay. Just for the record, you're now going outside 5 of the notebook here? 6 A. That's right. Well, I'm just pulling 7 my references. 8 Q. No, I understand, but just for the 9 record, you were going through a notebook with 10 documents pertaining to Mylan that you have reviewed 11 or rereviewed since your deposition was taken on 12 June 29, 2010, right? 13 A. That is correct. 14 Q. And now you've -- you have brought 15 another notebook here. What's the spine title on 16 that? 17 A. It says "references." It contains the 18 majority of the documents that I referenced. It 19 does not contain any additional documents. 20 Q. Okay. So when you say it contains the 21 majority of documents that are referenced, you mean 22 that are referenced in your report? 23 A. That is correct. 24 Q. And your report dated June 15, 2010 25 submitted in this case has an appendix with all of</p>	<p style="text-align: right;">Page 373</p> <p>1 it's directed to both the distributor and the 2 manufacturer? 3 A. It is my understanding based on my 4 experience that that is who it's directed towards, 5 that's what I used as a head of QA as my directive, 6 and it's what I would expect out of a contract 7 manufacturing company, somebody who made product for 8 me. 9 Q. Let me -- let me just make sure I 10 understand the basis here of your conclusion that 21 11 CFR section 211.22 is directed to both the 12 manufacturer of DIGITEK, Actavis, that had an ANDA 13 approved by the FDA and its distributor, Mylan. You 14 say you're referring to your own experience? 15 A. Correct. 16 Q. As head of QA. You were head of QA 17 for -- 18 A. Many companies, nine different -- 19 eight different companies. 20 Q. Within the Johnson & Johnson family? 21 A. Within the Johnson & Johnson family of 22 companies. 23 Q. Okay. And were any of those companies 24 distributors of a product? 25 A. Could you tell me what you are</p>

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<p style="text-align: right;">Page 374</p> <p>1 describing as the distributor? Define that for me, 2 please. 3 Q. Well, isn't that what we're talking 4 about in this case? 5 A. Yeah. But I'd like to understand your 6 understanding. 7 Q. Mylan -- it's your understanding that 8 Mylan was the distributor of DIGITEK, right? 9 A. I -- if I can answer your question. 10 Q. Is it your understanding that Mylan 11 was a distributor of DIGITEK? 12 A. Yes. 13 Q. Were any of the eight Johnson & 14 Johnson family companies for whom you were the 15 director of QA distributors of a product 16 manufactured by another company pursuant to an NDA 17 or an ANDA that had been approved by the FDA? 18 A. I don't recall any. 19 Q. So you had no experience as a director 20 of QA for a company that was a distributor like 21 Mylan? 22 MS. CARTER: Object to form. 23 A. As a head of QA, I do not recall us 24 being a distributor, and I'd have to really think 25 about it. We're talking about 30 years of</p>	<p style="text-align: right;">Page 376</p> <p>1 A. I -- for over a period of eight years 2 on and off, I audited probably on average 20 3 companies per year worldwide. 4 Q. For whom? 5 A. Johnson & Johnson corporate. 6 Q. You -- you audited companies who were 7 distributors of Johnson & Johnson products? 8 A. I -- I audited companies that were 9 similar to Mylan in that they would distribute 10 products that they manufactured and distributed 11 products that were manufactured by another company 12 who either did -- did in some instances hold the NDA 13 or -- but mostly did not hold the ANDA or NDA. 14 Q. Tell me about -- let's go through the 15 products. 16 A. I can't recall, sir. 17 Q. Let's go through the companies. 18 A. I went to 200 companies. 19 Q. Well, give me an example of a 20 situation where you audited some company that -- 21 that was in a position similar to Mylan distributing 22 a product manufactured by another company, in this 23 case, Actavis, who was the holder of an abbreviated 24 new drug application, ANDA, approved by the FDA. 25 Give me one example.</p>
<p style="text-align: right;">Page 375</p> <p>1 experience in that regard. Could you give me a 2 minute? I'd like to mentally go through the 3 companies I've worked for. 4 BY MR. KAPLAN: 5 Q. Absolutely. Because I want -- I want 6 you to have your memory refreshed. I want you to 7 testify to the best of your ability here today. I 8 want you to bring all of your experience to bear, 9 and I want the jury to be able to understand -- 10 A. Right. 11 Q. -- that when I say you, Mr. Kenny, in 12 all of your experience, have never been in the shoes 13 of Mylan as a distributor of a product manufactured 14 by a company like Actavis who is the holder of an 15 ANDA approved by the FDA, I want the jury to 16 understand that you have had no such experience. 17 A. Okay. 18 Q. And if that's not correct, you tell me 19 what's correct. 20 A. Okay. As the head of QA, I cannot 21 recall a product, as eight years in corporate, I did 22 audit companies, operating companies, that did 23 distribute product, market it, with -- and they did 24 not hold the ANDA or the NDA. 25 Q. Tell me about your experience.</p>	<p style="text-align: right;">Page 377</p> <p>1 A. I can't recall -- I do know that I had 2 done auditing for Cilag. I did auditing -- I 3 audited them. And they were in a position where 4 they had products, and I can't recall what they 5 were, that were manufactured by the holder of an 6 ANDA or an NDA, probably an NDA, but I can't tell 7 you what -- what products they were. But I did a 8 lot of audits. 9 Q. You mentioned one company, Cilag? 10 A. Cilag. 11 Q. Can you spell that for us? 12 A. C-I-L-A-G. 13 Q. Where is Cilag located? 14 A. Schaffhausen in Switzerland. 15 Q. Is Cilag subject to FDA regulations in 16 the United States? 17 A. They do when they export product to 18 the United States. 19 Q. What did Cilag distribute in the 20 United States? 21 A. I don't recall. 22 Q. Did they distribute a product in the 23 United States? 24 A. Yes, they most certainly did. 25 Q. But you don't know what product?</p>

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<p style="text-align: right;">Page 378</p> <p>1 A. I don't recall, sir.</p> <p>2 Q. Who manufactured the product?</p> <p>3 A. Well, they were the primary</p> <p>4 manufacturer, but they used contract manufacturers</p> <p>5 as --</p> <p>6 Q. Well, that's a different situation</p> <p>7 than Mylan, isn't it?</p> <p>8 A. No. I understand, but you --</p> <p>9 Q. Isn't it?</p> <p>10 A. No. They did --</p> <p>11 Q. Mylan is not the primary manufacturer</p> <p>12 of DIGITEK, is it?</p> <p>13 A. Can I explain?</p> <p>14 Q. Is Mylan the primary manufacturer of</p> <p>15 DIGITEK?</p> <p>16 A. They are not.</p> <p>17 Q. So if Cilag was the primary</p> <p>18 manufacturer of some product that you can't</p> <p>19 remember, it's not an equivocal situation?</p> <p>20 A. No, no, no. No. Cilag did one of two</p> <p>21 things, they either were the manufacturer and</p> <p>22 distributor of the product of which some of those</p> <p>23 products came to the United States of which when</p> <p>24 I -- I audited them, I would use current GMP. They</p> <p>25 also distributed product that were where the</p>	<p style="text-align: right;">Page 380</p> <p>1 distributed products manufactured by non Johnson &</p> <p>2 Johnson companies?</p> <p>3 A. That is correct.</p> <p>4 Q. But you don't know what -- what</p> <p>5 products?</p> <p>6 A. I don't recall.</p> <p>7 Q. And you don't know -- you don't know</p> <p>8 what other manufacturers' products Cilag</p> <p>9 distributed?</p> <p>10 A. I do not. I cannot recall.</p> <p>11 Q. And did Cilag have a quality agreement</p> <p>12 with -- with manufacturers for whom it distributed</p> <p>13 products?</p> <p>14 A. This was in '82. I don't recall.</p> <p>15 Q. Did you ding them if they didn't?</p> <p>16 A. Would I ding them? At that particular</p> <p>17 point, I probably would not have.</p> <p>18 Q. Did they operate under a supply and</p> <p>19 distribution agreement?</p> <p>20 A. The -- I don't recall.</p> <p>21 Q. But you went to Switzerland to audit</p> <p>22 Cilag; is that right?</p> <p>23 A. That is correct.</p> <p>24 Q. And it's your understanding that Cilag</p> <p>25 was responsible as a distributor of a product that</p>
<p style="text-align: right;">Page 379</p> <p>1 holder -- the manufacturer was the holder of an ANDA</p> <p>2 or an NDA. And you know, there's others, Janssen</p> <p>3 Pharmaceutical, even more -- I did more for them</p> <p>4 than Cilag.</p> <p>5 Q. Wait a minute. You were asked to do a</p> <p>6 GMP audit of a company called Cilag for your</p> <p>7 employer, Janssen?</p> <p>8 A. Johnson & Johnson.</p> <p>9 Q. Is it Janssen?</p> <p>10 A. Janssen is another company, a larger</p> <p>11 company than Cilag.</p> <p>12 Q. Did you audit Cilag in your capacity</p> <p>13 as an employee of Johnson & Johnson?</p> <p>14 A. That's correct.</p> <p>15 Q. Why?</p> <p>16 A. Because it was part of our</p> <p>17 responsibilities is to audit all companies</p> <p>18 worldwide. That was our -- our mission.</p> <p>19 Q. Is Cilag a Johnson & Johnson company?</p> <p>20 A. Yes, it is.</p> <p>21 Q. What -- what -- what products did it</p> <p>22 distribute?</p> <p>23 A. I don't -- I don't recall, sir,</p> <p>24 anymore.</p> <p>25 Q. But you're telling me that Cilag</p>	<p style="text-align: right;">Page 381</p> <p>1 you can't remember for a company, a manufacturer</p> <p>2 that you can't remember, subject to FDA's good</p> <p>3 manufacturing practice regulations?</p> <p>4 A. I -- in thinking back, I probably</p> <p>5 didn't ask that question of Cilag or Janssen at that</p> <p>6 particular point.</p> <p>7 Q. What question didn't you ask?</p> <p>8 A. I did not ask to see the quality</p> <p>9 agreement.</p> <p>10 Q. Can you give me any other examples of</p> <p>11 any experience that you've had with a company that</p> <p>12 you say was in the shoes of Mylan, in other words,</p> <p>13 being a distributor of a product manufactured by</p> <p>14 another company, in this instance, Actavis, pursuant</p> <p>15 to an ANDA approved by the FDA?</p> <p>16 A. Janssen Pharmaceutical.</p> <p>17 Q. Is another example?</p> <p>18 A. Yes, similar to Cilag.</p> <p>19 Q. Pardon?</p> <p>20 A. Similar to Cilag.</p> <p>21 Q. What -- what -- tell me about the</p> <p>22 Janssen situation.</p> <p>23 A. It would be much the same. I would</p> <p>24 audit the Janssen headquarters and I -- which is</p> <p>25 also the -- a manufacturing site. And I would audit</p>

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<p style="text-align: right;">Page 382</p> <p>1 some of their own manufacturers and some of their 2 contract manufacturers. 3 Q. When you use the term again, "contract 4 manufacturer," and you use that in conjunction with 5 Janssen, are -- are you telling me that there were 6 instances where Janssen held an NDA or an ANDA and 7 contracted with others to manufacture the product? 8 A. That is correct. 9 Q. Is it your understanding that Mylan 10 did not hold the ANDA for DIGITEK? 11 A. It is my understanding they did not 12 hold the ANDA or NDA. 13 Q. So that's different than the Jantzen 14 situation? 15 A. In that particular situation. But 16 they also -- I'm sorry, I'm answering your 17 questions. Go ahead. 18 Q. That's -- that's fine. Getting back 19 to the CFR that you referred to, what -- what is it 20 here that you say has bearing on Mylan's 21 responsibility? 22 A. Okay. Can I read it aloud? 23 Q. Why don't you first show it to me, 24 show me exactly what it is. 25 A. (Handing). Section 22.</p>	<p style="text-align: right;">Page 384</p> <p>1 manufacturers and distributors? 2 A. I know it does. 3 Q. How do you know that? 4 A. Because that's the way I was trained. 5 Q. Can you show me something in -- in the 6 regulations here that says this is applicable to 7 distributors and to manufacturers of products that 8 are approved by the FDA pursuant to an ANDA or an 9 NDA? 10 A. I am not a legal expert. I cannot 11 point to that. 12 Q. So if you are wrong, then, if this 13 only applies to a manufacturer and not a 14 distributor, that would affect your opinion? 15 A. I am not wrong, but it would. 16 Q. Are you familiar with the distribution 17 procedures that are set forth in the GMPs? 18 A. Reasonably familiar, but I always 19 reread them to refamiliarize myself when I have 20 questions. 21 Q. The regulation that you were referring 22 to is part of section two -- 23 A. Do you want me to give you the 24 specific thing? 25 Q. Let me just see that.</p>
<p style="text-align: right;">Page 383</p> <p>1 Q. Were you going to read the highlighted 2 portions? 3 A. No, the whole thing is actually 4 important. Basically what it does is tell the 5 reader that there are certain requirements for 6 quality systems that needed to be established and 7 documented, and that's it. 8 Q. Okay. Now, are you -- are you 9 familiar with GMPs that are applicable to 10 distributors of outsourced products? 11 A. The GMPs are applicable to both the 12 distributor and the person who manufactures the 13 product. 14 Q. Where -- where -- where do you derive 15 that understanding? 16 A. I derive it from that statement. 17 Q. From which statement? 18 A. The quality -- section 22. 19 Q. "There shall be a quality control unit 20 that shall have the responsibility and authority to 21 approve or reject all components, drug product 22 containers, closures, and processed materials." Is 23 that the statement? 24 A. Yes. 25 Q. And you think that applies to both</p>	<p style="text-align: right;">Page 385</p> <p>1 A. Sure. Let me turn the page for you. 2 Q. So, you are also familiar with, I take 3 it, 21 CFR 210.1 regarding the status of good 4 manufacturing practice regulations? 5 A. I have to reread it. 6 Q. Well, I'll just -- I'll read you 7 section A under section 210.1, and ask you whether 8 you agree with this. The regulation set forth in 9 this part and in parts 211 through 226 of this 10 chapter, "contain the minimum current good 11 manufacturing practice for methods to be used in and 12 the facilities or controls to be used for the 13 manufacture, processing, packing, or holding of a 14 drug to ensure that such drug meet the requirements 15 of the act as to safety and has the identity and 16 strength and meets the quality and purity 17 characteristics that it purports or is represented 18 to possess." Does that sound familiar to you? 19 A. Yes. 20 Q. Okay. That's the manufacturer's 21 responsibility, isn't it? 22 A. That is the manufacturer's or the 23 distributor's responsibilities. 24 Q. And -- and again, with all due 25 respect, sir, where do you see that that is a</p>

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<p style="text-align: right;">Page 386</p> <p>1 distributor's responsibility?</p> <p>2 A. I did not see that word in there. It</p> <p>3 is my understanding that it does include a</p> <p>4 distributor of the product.</p> <p>5 Q. And that understanding is derived from</p> <p>6 what?</p> <p>7 A. From my experience and my training.</p> <p>8 Q. In all of the documents you reviewed</p> <p>9 regarding FDA inspections regarding DIGITEK, did you</p> <p>10 ever see the FDA inspect Mylan?</p> <p>11 A. No, I did not.</p> <p>12 Q. Why not?</p> <p>13 A. I don't know, you have to ask them. I</p> <p>14 don't know.</p> <p>15 Q. Well, you have a lot of experience,</p> <p>16 don't you?</p> <p>17 A. I have experience but not as a -- from</p> <p>18 an FDA standpoint. And whether they were audited or</p> <p>19 not, I don't know. Perhaps they were audited or</p> <p>20 inspected.</p> <p>21 Q. Did you see anything that -- that led</p> <p>22 you to believe that the FDA was ever critical of</p> <p>23 Mylan?</p> <p>24 A. I didn't see any reference to Mylan</p> <p>25 where there was criticism.</p>	<p style="text-align: right;">Page 388</p> <p>1 let's go back to that situation you were describing</p> <p>2 to me before about a company called Cilag.</p> <p>3 A. Cilag.</p> <p>4 Q. C-I-L-A-G, and Janssen, were they</p> <p>5 considered authorized distributors of record?</p> <p>6 A. I don't know what legally they were</p> <p>7 categorized as.</p> <p>8 Q. So how would you conduct an audit of</p> <p>9 those companies without knowing what their legal</p> <p>10 status or -- or the requirements were?</p> <p>11 A. Based upon my training, they were</p> <p>12 required to meet all aspects of the GMPs, so the</p> <p>13 compliment of the two companies had to meet every</p> <p>14 requirement.</p> <p>15 Q. Fundamental to your opinions in this</p> <p>16 case is the legal status of the party involved,</p> <p>17 right?</p> <p>18 A. I'm not sure if it is.</p> <p>19 Q. Well, the legal status of the party</p> <p>20 involved carries with it certain legal requirements,</p> <p>21 doesn't it?</p> <p>22 A. But this is going beyond what I am</p> <p>23 looking at. I am looking at, based upon my</p> <p>24 training, what the expectation is from the FDA and</p> <p>25 business norms, expected business norms, what the</p>
<p style="text-align: right;">Page 387</p> <p>1 Q. By the FDA?</p> <p>2 A. By the FDA.</p> <p>3 Q. Okay. Moving right along with your</p> <p>4 book here of the Mylan documents that you reviewed</p> <p>5 or rereviewed since your deposition was initially</p> <p>6 taken on June 29, 2010, please hand me the next</p> <p>7 document.</p> <p>8 A. This really is -- well, it's basically</p> <p>9 the same. Let me show you it to you. It's an</p> <p>10 unsigned version of a -- of a similar subject.</p> <p>11 Q. It may be in fact exactly the same.</p> <p>12 A. It may be.</p> <p>13 Q. It bears the Bates number -- it's a</p> <p>14 one-page document with Bates number MLYN 000032343,</p> <p>15 which was I believe the second page that was</p> <p>16 attached to the earlier document, right?</p> <p>17 A. I am sure that's right.</p> <p>18 Q. Okay. So, again, there is nothing</p> <p>19 here that's remarkable to you?</p> <p>20 A. Nothing.</p> <p>21 Q. Nothing that bears upon your opinion?</p> <p>22 A. Correct.</p> <p>23 Q. Nothing that you found enlightening?</p> <p>24 A. No, nothing enlightening.</p> <p>25 Q. Okay. In all of your experience,</p>	<p style="text-align: right;">Page 389</p> <p>1 control systems that should be in place to meet all</p> <p>2 aspects and conditions of GMP.</p> <p>3 Q. When you refer to "business norms,"</p> <p>4 what's -- what's the foundation for your arriving</p> <p>5 at, quote, what "business norms" are?</p> <p>6 A. When I review a company and I review</p> <p>7 for business norms, I would recommend to them</p> <p>8 perhaps improvement based upon benchmarking other</p> <p>9 companies. It wouldn't be an observation, it would</p> <p>10 be part of continual improvement process.</p> <p>11 Q. Just refer me to the underlying</p> <p>12 documents that establish the business norms in your</p> <p>13 area of expertise.</p> <p>14 A. It would be my informal understanding</p> <p>15 of best practice.</p> <p>16 Q. Is there any document whatsoever that</p> <p>17 establishes "business norms"?</p> <p>18 A. Absolutely nothing.</p> <p>19 Q. This is all kind of up in your head,</p> <p>20 right?</p> <p>21 A. When it comes to success models, it is</p> <p>22 in my head based upon the companies or experience</p> <p>23 that I've had.</p> <p>24 Q. So -- so when you -- so when you use</p> <p>25 the term and you refer to business norms, that's</p>

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<p style="text-align: right;">Page 390</p> <p>1 whatever Kenny says the norm shall be?</p> <p>2 A. That is what -- in that regard, I</p> <p>3 wouldn't put it that way, but I understand your</p> <p>4 question, and I would say, yes, it's based upon</p> <p>5 my -- it's -- it's much like a consultant going in</p> <p>6 and saying it does not necessarily violate GMP, but</p> <p>7 it's a good thing to do.</p> <p>8 Q. It is twelve o'clock. Do you want</p> <p>9 to --</p> <p>10 A. I'll tell you if I'm not holding up</p> <p>11 well.</p> <p>12 (Handing.) This is much the same.</p> <p>13 Q. Okay. You've just handed me another</p> <p>14 document that you've reviewed or rereviewed since</p> <p>15 your deposition of June 29, 2010. And it is a</p> <p>16 previously marked Exhibit M-7 from the deposition of</p> <p>17 Susie Wolf that bears Bates numbers MYLN 000032473</p> <p>18 through 75. By the way, you did not read the Susie</p> <p>19 Wolf deposition, did you?</p> <p>20 A. Susie Wolf. I don't recall. I'd have</p> <p>21 to -- I did not reread it, perhaps I read it earlier</p> <p>22 and I found nothing --</p> <p>23 Q. Wait a minute. Wait a minute. In</p> <p>24 your previous deposition, you said the only Mylan</p> <p>25 deposition you read was Chuck Koons. Earlier today</p>	<p style="text-align: right;">Page 392</p> <p>1 first page, right?</p> <p>2 A. Yes.</p> <p>3 Q. And what -- what -- and then you put a</p> <p>4 big checkmark on the second page?</p> <p>5 A. Yes.</p> <p>6 Q. You have a circle with a question mark</p> <p>7 on it?</p> <p>8 A. I don't know what that meant. That</p> <p>9 was reviewed a while back.</p> <p>10 Q. So I take it there's nothing about</p> <p>11 this Exhibit M8 that you found remarkable,</p> <p>12 enlightening, or had any bearing upon any opinions</p> <p>13 that you've given in this case?</p> <p>14 A. That is correct. Do you want to see</p> <p>15 things that I had read that are not --</p> <p>16 Q. Well, I want to know what it is that</p> <p>17 you have done since your deposition was taken on</p> <p>18 June 29, 2010 by way of research, review, testing,</p> <p>19 discussions with counsel, anything that you've done</p> <p>20 that you think, you know, was significant or not</p> <p>21 significant. I don't care. I just want to know</p> <p>22 what you've done.</p> <p>23 A. But if I reread a document to</p> <p>24 familiarize myself with it, it didn't change</p> <p>25 anything, you have no interest in looking at it.</p>
<p style="text-align: right;">Page 391</p> <p>1 you said oh, no, no, I was mistaken. I think I read</p> <p>2 Mike Adam, and at least I reread Mike Adams. That's</p> <p>3 one of the documents here. And then I said, well,</p> <p>4 have you read any other Mylan depositions, and you</p> <p>5 said no.</p> <p>6 A. And your question is?</p> <p>7 Q. You haven't read any other Mylan</p> <p>8 depositions, have you?</p> <p>9 A. No, I have not read Susie Wolf's</p> <p>10 deposition.</p> <p>11 Q. Is there anything about this document</p> <p>12 marked Exhibit M7 that you found remarkable?</p> <p>13 A. Nothing.</p> <p>14 Q. Nothing enlightening?</p> <p>15 A. Nothing enlightening.</p> <p>16 Q. Nothing that bears on any opinion that</p> <p>17 you have rendered in this case, right?</p> <p>18 A. That is correct.</p> <p>19 Q. The next document that you have handed</p> <p>20 me is marked Exhibit M8. Also from the deposition</p> <p>21 of Susie Wolf, with Bates numbers MYLN 000032477</p> <p>22 through 79. It looks to me like your handwriting on</p> <p>23 the front. It says "done" with a big red checkmark?</p> <p>24 A. It just means I've read it.</p> <p>25 Q. And then you've got a line through the</p>	<p style="text-align: right;">Page 393</p> <p>1 Q. Unless there was something significant</p> <p>2 or you learned something or it reinforced --</p> <p>3 A. All of these were that.</p> <p>4 Q. When you say all of these were, we're</p> <p>5 getting toward the end here?</p> <p>6 A. Yeah. We head towards the end, it's</p> <p>7 kind of like anything else, either I have read it,</p> <p>8 and you know, I understand it, et cetera, and I've</p> <p>9 factored that in accordingly into my expert opinion</p> <p>10 or my report.</p> <p>11 Q. And if it was really significant, it</p> <p>12 would be among the 60 documents that you have listed</p> <p>13 in appendix B to your report of June 15, 2010 as the</p> <p>14 referenced documents, correct?</p> <p>15 A. That is correct. And -- so that's</p> <p>16 what we're going through now. It's kind of the tail</p> <p>17 ends of this. That's why --</p> <p>18 Q. Okay. Well, we can do this. In -- in</p> <p>19 the tail end of these documents that are in this</p> <p>20 notebook, is there anything that jumps off the page</p> <p>21 at you?</p> <p>22 A. I really would like to look at it to</p> <p>23 make sure I can answer that.</p> <p>24 Q. Okay. And you know what I mean by</p> <p>25 that?</p>

24 (Pages 390 to 393)

<p style="text-align: right;">Page 394</p> <p>1 A. I know exactly what you mean. 2 MS. CARTER: Do you want him to do 3 that during lunch? 4 A. It will only take me a couple of 5 minutes. 6 MR. KAPLAN: Why don't we do that 7 right now, and then we can get through this 8 notebook, and then we'll move on to another 9 subject after lunch. We'll stay on the 10 record. 11 A. To answer your consistent question, 12 there is nothing remarkable, and it had no effect, 13 the new documents had no effect on my report. 14 Q. Okay. And of these remaining 15 documents, tell me which ones are new to you. 16 A. Well, a lot of them have to do with 17 UDL. And again, as I explained, my process was to 18 just print these up. And so I just -- when in 19 doubt, I printed them, I looked at them. If there 20 is nothing remarkable, there is zero on it. If 21 there was something remarkable, there may be a note, 22 even that may have no importance. 23 Q. Okay. So there is no either new 24 document pertaining to Mylan that you reviewed since 25 your deposition of June 29, 2010 or any old Mylan</p>	<p style="text-align: right;">Page 396</p> <p>1 you, and I want to make sure you bring everything 2 with you? 3 A. Which I have. 4 Q. Okay. So let's go through the 5 documents requested in the amended notice of the 6 video deposition. This is what we call like a 7 subpoena duces tecum, in other words, the witness is 8 requested to bring these documents. And you told me 9 you would do that, and now you're telling me you 10 have brought them, right? 11 A. That is correct. 12 Q. Okay. So number one asks for your 13 current curriculum vitae or résumé. 14 A. Right. 15 Q. Is there anything -- it's in that 16 report, isn't it? 17 A. That's it. 18 Q. And that's it? 19 A. Yes. 20 Q. So what -- what is on your CV in the 21 report of June 15, 2010 is accurate, right? 22 A. That is correct. 23 Q. And it's up-to-date, right? 24 A. That is correct. 25 Q. All right. We'll -- we'll go through</p>
<p style="text-align: right;">Page 395</p> <p>1 document that in any way was remarkable to you? 2 A. There was nothing. 3 Q. All right. How about some lunch? 4 A. Sounds good. 5 Q. Not here yet. Okay. Well, we can 6 take a restroom break and relax a little bit. 7 A. Do you want to take a short lunch? 8 THE VIDEOGRAPHER: We're off the 9 record. The time is -- 10 THE WITNESS: Do you want to continue 11 until lunch. 12 BY MR. KAPLAN: 13 Q. I'm good to go. Are you good to go? 14 A. I'll raise my hand. 15 Q. Okay. You raise your hand. I told 16 you earlier I don't want to put you -- 17 A. It's a challenge. 18 Q. I don't want to put you through 19 anything unnecessarily. Okay. Let's -- let's do 20 this: Remember at the end of your deposition on 21 June 29, 2010, I simply asked you to make sure that 22 you went through the documents you were requested to 23 bring to your deposition, which you hadn't brought 24 in their entirety the first time around. And I 25 said, now, I'm going to have a chance to examine</p>	<p style="text-align: right;">Page 397</p> <p>1 some of that -- 2 A. Let me make sure it's up-to-date, sir. 3 Q. Actually, you say in your report on 4 Page 3, that your complete CV is at appendix A of 5 your report, so that would be on page 37 and 38, 39, 6 40. So 37 through 40, that is your CV, right? 7 A. Yes. And that is a complete CV. Same 8 as what I brought here (indicating). 9 Q. Okay. Number two asks that you bring 10 all correspondence and communication between the 11 witness, you, or anyone acting on the witness' 12 behalf, and attorneys representing plaintiffs in 13 this Digitek litigation. So have you brought that? 14 A. Could you repeat that? I'm sorry. I 15 was reading. 16 Q. Okay. You -- you have had this -- 17 A. I have had that, and I went through it 18 line by line. 19 Q. And I think Meghan told me you did. I 20 appreciate you your being conscientious about that. 21 Correspondence and communication between you, the 22 witness, or anyone acting on your behalf. 23 A. Yes. 24 Q. And anyone else from SpyGlass or any 25 of your partners or business associates, and</p>

25 (Pages 394 to 397)

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<p style="text-align: right;">Page 398</p> <p>1 attorneys representing plaintiffs in this 2 DIGITEK litigation. 3 A. That's correct. 4 Q. Okay. Do you have that 5 correspondence? 6 A. Oh, yeah. Oh, I thought you started 7 going through it. It's going to take me a couple of 8 minutes just to -- I mean, I have three volumes of 9 this stuff. (Hanging.) 10 Q. Okay. By the way, you work pretty 11 closely with your colleague, Sal Romano, in this 12 case? 13 A. I do at times. 14 Q. You did in this case? 15 A. Initially I did. 16 Q. Well, you did up until ten days before 17 you issued your final opinion, didn't you? 18 A. If that's the date. I -- perhaps it 19 was ten days. 20 Q. But you and Sal Romano collaborated on 21 the expert opinions that finally came out under your 22 name, right? 23 A. Yes. He was basically a consultant to 24 me, if you will, and then it was determined that -- 25 originally we had discussed both of us signing a</p>	<p style="text-align: right;">Page 400</p> <p>1 A. Yes. 2 Q. Okay. And did you bring the -- the 3 correspondence between you and Sal? 4 A. I brought all of the correspondence 5 between Sal and I, yes. 6 Q. Oh, did you? Okay. Is that in this 7 folder here? 8 A. That would be in the e-mails. 9 Q. Okay. So I have a folder here, and 10 I'm going to ask the court reporter to mark it as 11 Exhibit 110. 12 (Whereupon, Exhibit 110, Folder, was 13 marked for identification as of today's 14 date.) 15 BY MR. KAPLAN: 16 Q. So this folder labeled "e-mails," 17 which has been marked as Exhibit 110, contains all 18 the correspondence between you and any of the 19 Plaintiff's lawyers for whom you are working here? 20 A. That is correct. 21 Q. And between you and Sal Romano? 22 A. That is correct. 23 Q. And who else collaborated on -- on 24 your opinions in this case? 25 A. Nobody else.</p>
<p style="text-align: right;">Page 399</p> <p>1 deposition. 2 Q. Signing the report? 3 A. Signing the report, rather, and he 4 felt he could not meet the legal schedule and 5 therefore had to -- had to pull back. 6 Q. But he was your partner in -- in 7 getting to -- 8 A. I wouldn't use the name "partner," but 9 he participated. 10 Q. He was part of the SpyGlass group? 11 A. Part of the SpyGlass group. 12 Q. He has billed for his time? 13 A. That -- that is correct. 14 Q. At \$430 an hour as well, right? 15 A. That is correct. 16 Q. So essentially, the Plaintiff's 17 lawyers got two for one here, right, but charged 18 separately? 19 A. Or one for two, but yeah. 20 Q. Yeah. So between the two of you, 21 that's \$860 an hour? 22 A. When we work -- yeah, right. If we 23 work together, it would be -- it would add up to 24 that. 25 Q. \$860?</p>	<p style="text-align: right;">Page 401</p> <p>1 Q. You had mentioned another person at 2 the deposition on June 29, 2010 who engaged you or 3 introduced you to the Motley Rice firm. 4 A. Yeah, John Kowalski. 5 Q. And who is John Kowalski? 6 A. I worked with John 30 years ago, 25 7 years ago, and he's -- I think he has his own 8 independent consulting company. 9 Q. Okay. What was his role in this case? 10 A. Giving us a telephone number of who to 11 call. 12 Q. So he didn't participate 13 substantively? 14 A. Not in the least bit. I didn't even 15 talk to him. 16 Q. And he hasn't billed for any of his 17 work in this case? 18 A. No, he has not. 19 Q. Okay. How about Russ Somma, 20 S-O-M-M-A? 21 A. Yeah. 22 Q. Okay. Was he part of your team? 23 A. No, he was not part of the group. 24 Q. Who is Russ Somma? 25 A. Russ Somma is an independent</p>

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<p style="text-align: right;">Page 402</p> <p>1 consultant who is an expert on tableting, among 2 other things. 3 Q. Well, didn't you recommend to the 4 plaintiff's lawyers in this case that Russ Somma be 5 included as part of the, quote, evaluation team? 6 A. We recommended -- we offered his name 7 as somebody that based upon our research, was 8 qualified. 9 Q. And you recommended that Russ Somma be 10 part of the "evaluation team," right? 11 A. No, I would not say that. I 12 recommended that they talk to him. I don't have 13 first-hand -- 14 Q. You did say that, didn't you? 15 A. What's that? 16 Q. Well, I'm looking at an e-mail here, 17 and I'm going to show it to you, from SpyGlass 18 Group, Inc., that's you? 19 A. Yeah. 20 Q. Dated March 23, 2010 to Meghan Johnson 21 Carter, that's Meghan sitting here, and Sal Romano, 22 with copies to Sandy Summers, Fred Thompson, Pete 23 Miller, and SpyGlass Group, Inc., subject, drug 24 tableting expert. And it says -- you tell me if I'm 25 wrong -- I'm going to show it to you. "I recommend</p>	<p style="text-align: right;">Page 404</p> <p>1 A. He's a vice president of the SpyGlass 2 Group, that's his title. 3 Q. And you are the managing director of 4 the SpyGlass Group? 5 A. That is correct. 6 Q. That is a corporation? 7 A. That is a corporation. 8 Q. That does work as expert witness in 9 litigation? 10 A. That does consulting work. 11 Q. And work as expert witness in 12 litigation? 13 A. Recently. Recently. 14 Q. Actually, the expert witness work is 15 more lucrative than the consulting work? 16 A. It gets billed at a higher rate when 17 it's billed. 18 Q. When you worked for Johnson & Johnson, 19 were you paid \$430 an hour? 20 A. No, I was not. 21 Q. How much were you paid per hour? 22 A. I don't know. I made on average a 23 quarter of a million dollars a year. You figure out 24 per hour what that is since 1990. 25 Q. It wasn't 430 an hour?</p>
<p style="text-align: right;">Page 403</p> <p>1 that you consider Russ Somma as part of the 2 evaluation team." 3 A. Yes, I said that, I'm sure. I mean, 4 it's in there, and I did recommend that they 5 consider him, that based upon -- I'm sorry, go 6 ahead. 7 Q. Go ahead. 8 A. No. 9 Q. What else did you want to add? What 10 happened with Mr. Somma? 11 A. They engaged him and had a contract 12 with him and they engaged him. 13 Q. So is he part of the evaluation team? 14 A. He's not part of any team that I'm a 15 part of. 16 Q. Well, did he participate in the work 17 that you and Sal Romano did in arriving at opinions 18 in this case? 19 A. No, zero, absolutely zero. 20 Q. Mr. Romano is a PhD, is he? 21 A. That is correct. 22 Q. And what does he have his PhD in? 23 A. Analytical chemistry. 24 Q. And he is the vice president of the 25 SpyGlass Group?</p>	<p style="text-align: right;">Page 405</p> <p>1 A. I have no idea. I'd have to 2 extrapolate it out. It was probably 5 cents an hour 3 based upon the number of hours that I worked. 4 Q. Okay. So what was Mr. or Dr. -- is it 5 Dr. Romano? 6 A. Yes. 7 Q. What was Dr. Romano's role? 8 A. Originally it was to offer expert 9 opinion. 10 Q. On what? 11 A. On this, the case that I worked on 12 that -- that we're discussing today. 13 Q. Okay. You have different areas of 14 expertise? 15 A. Yes, that is correct. 16 Q. Your expertise you say is in -- 17 A. Quality systems. 18 Q. Quality systems. And his expertise is 19 in? 20 A. His expertise is in the laboratory and 21 in managing a world-class company from a corporate 22 standpoint. 23 Q. What world-class company did he 24 manage? 25 A. Johnson & Johnson. He was the head of</p>

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<p style="text-align: right;">Page 406</p> <p>1 quality and compliance services for, I don't know, 2 10 years or so at the company. 3 Q. What -- what did he contribute to the 4 opinions that you rendered in your report of 5 June 15, 2010? 6 A. Could you -- can I ask you to rephrase 7 that? And it's an important question. Rephrase it. 8 Q. I'll have the court reporter to ask it 9 back again and you tell me. 10 (Record read.) 11 A. Nothing. 12 Q. Well, what did he bill for? 13 A. He billed for review, as I billed for 14 review. 15 Q. What was his review? 16 A. His review -- he reviewed the same 17 things that I reviewed. 18 Q. So you worked kind of in double 19 harness? 20 A. Correct. We were in parallel. 21 Q. But you didn't find his input helpful 22 to you in arriving at opinions? 23 A. I found his -- his opinions helpful 24 and that they reinforced what I understood to be the 25 business, and I understood the requirements. He did</p>	<p style="text-align: right;">Page 408</p> <p>1 don't know, towards June 3rd or something like that. 2 She reviewed a copy on June 3rd, never saw -- never 3 saw a single document other than I flashed in front 4 of them the first document that I was working on, 5 that I was working on. 6 Q. When you say "I flashed in front of 7 them" -- 8 A. Flashed, meaning we had a meeting, 9 very first meeting -- 10 Q. Who is we? 11 A. Sal Romano and myself, Pete Miller and 12 Meghan. We had a meeting and they asked me how is 13 it going? And I said fine. And I gave them my 14 approach and I said my approach is very analytical. 15 I don't jump to conclusions, but I logically go 16 through it, and at the end of it, I will make some 17 type of a conclusion. And I showed them what I was 18 working on, I'm taking all of the facts, I'm 19 compiling them, I'm organizing them, which 20 ultimately became the tables or some edits became 21 the tables. And based upon that which was the first 22 draft of my report, then I started adding meat to 23 the report narrative. And at that point, Sal would 24 review the narrative. We met twice. 25 Q. When was it that you said you -- you</p>
<p style="text-align: right;">Page 407</p> <p>1 reinforce my opinion. In other words -- yeah, 2 that's it. 3 Q. What -- what -- what opinion did he 4 reinforce for you? 5 A. Depends upon the section of the 6 document. He read my report and then we discussed 7 it. As a matter of fact, you have a copy of the 8 report where we met and he read, and you know, he 9 gave me his input. Most of it was typing and 10 spelling kind of thing. 11 Q. He helped you write the report? 12 A. He assisted. I would have to say yes, 13 yes. 14 Q. How did he help you write the report? 15 A. Well, he participated in it. 16 Q. Who was the original drafter of the 17 report? 18 A. I am. I am the drafter. I am the 19 writer. He was a reviewer. 20 Q. Meghan was a reviewer? 21 A. No, Meghan didn't review anything. 22 Q. She didn't? 23 A. No. 24 Q. Never did? 25 A. Oh, yeah. I sent her one copy, I</p>	<p style="text-align: right;">Page 409</p> <p>1 met with Meghan Carter and Pete Miller to show them 2 your report? 3 A. I'd have to go through the e-mail, but 4 it -- it should be there. 5 Q. But -- but you didn't meet with them 6 before your report was finalized? 7 A. Yes. That is correct. 8 Q. And they reviewed that report? 9 A. They did not review the report, they 10 didn't even look at it. They didn't see a word in 11 it, nothing, zero. I had -- I had something right 12 here, I'm explaining, please. 13 Q. Okay. Sure. 14 A. This is very important, I understand 15 that. I had a document which is quite similar to 16 the attachments that are in there (indicating), 17 which you have electronic copies of and you have 18 electronic copies of every single change that I made 19 because I was really particular about it, okay? I 20 had that document here (indicating), and they said 21 what -- how are you doing? I said I am reviewing 22 it. I said I'm compiling it. I said here is my 23 approach. Is it -- I asked them if it was logical, 24 and they said sure, go for it. 25 Q. So they didn't review -- Meghan Carter</p>

28 (Pages 406 to 409)

<p style="text-align: right;">Page 410</p> <p>1 or Pete Miller did not review your report?</p> <p>2 A. Sir, I will answer this again, but</p> <p>3 it's not necessarily to repeat it. They looked at</p> <p>4 no report other than the June 3rd or whatever it</p> <p>5 was, report, and that was it.</p> <p>6 Q. Okay. So they looked at a report on</p> <p>7 June 3rd?</p> <p>8 A. June 3rd, yeah, or thereabouts.</p> <p>9 Q. The Plaintiff's lawyers did?</p> <p>10 A. Yes.</p> <p>11 Q. They reviewed the report that you gave</p> <p>12 them on June 3rd?</p> <p>13 A. That is correct.</p> <p>14 Q. And they had input into your final</p> <p>15 report, didn't they?</p> <p>16 A. They had some wordsmithing assistance.</p> <p>17 Q. They -- they gave you direction as to</p> <p>18 what -- what should be said in the final report?</p> <p>19 A. No. They challenged me, quite</p> <p>20 honestly. They challenged me as to whether or</p> <p>21 not -- they said, remember, and they gave me some</p> <p>22 rules, if you will, as an expert that all of your</p> <p>23 opinions have to be based upon facts and data and</p> <p>24 experience. And I wanted to make sure that I</p> <p>25 wasn't, you know, shooting from the hip. So it was</p>	<p style="text-align: right;">Page 412</p> <p>1 Q. You got substantive input from the</p> <p>2 Plaintiff's lawyers on what should be contained in</p> <p>3 your opinion.</p> <p>4 A. I would not call that substantive.</p> <p>5 No, I did not get substantive opinion or direction.</p> <p>6 Q. So it's your testimony, then, you got</p> <p>7 no substantive direction from any of the Plaintiff's</p> <p>8 lawyers as to what should be contained in your</p> <p>9 report of June 15, 2010?</p> <p>10 A. Yes. Thank you for phrasing it that</p> <p>11 way. Yes, that is correct.</p> <p>12 Q. No Plaintiff's lawyer told you</p> <p>13 anything about what you should say as to Mylan?</p> <p>14 A. Absolutely not, zero.</p> <p>15 Q. Let's -- why don't we -- why don't we</p> <p>16 break now. It's 12:30 and we'll have lunch and</p> <p>17 we'll come back.</p> <p>18 THE VIDEOGRAPHER: We're off the</p> <p>19 record. The time is 12:34. This is the end</p> <p>20 of tape 2.</p> <p>21 (Luncheon recess taken.)</p> <p>22 A F T E R N O O N S E S S I O N</p> <p>23 (1:33 p.m.)</p> <p>24</p> <p>25 THE VIDEOGRAPHER: We're back on the</p>
<p style="text-align: right;">Page 411</p> <p>1 really to -- just to make sure I wasn't over</p> <p>2 extending my -- my expert experience.</p> <p>3 Q. They told you that all of your</p> <p>4 opinions had to be based on facts, data, and what,</p> <p>5 research?</p> <p>6 A. Well, I'm paraphrasing. They</p> <p>7 didn't -- we didn't discuss it that way, but the way</p> <p>8 I interpreted it is that my opinion need to be based</p> <p>9 upon my expert -- or the experience that I had which</p> <p>10 would render me a -- an expert witness. And that --</p> <p>11 yeah, sorry.</p> <p>12 Q. And -- and you got specific direction</p> <p>13 from the plaintiffs' attorneys as to what should be</p> <p>14 contained in the report, didn't you?</p> <p>15 A. I -- no. I had some I would say</p> <p>16 grammar -- Meghan, if I recall, just -- it was</p> <p>17 grammar. I don't think there was anything else.</p> <p>18 And I believe there might have been a discussion</p> <p>19 with Pete on whether or not I -- that's an expert</p> <p>20 opinion or is that your opinion? And I changed, I</p> <p>21 don't know, a paragraph, two paragraphs, if that,</p> <p>22 and rephrased it. I'll give you an example.</p> <p>23 Q. You're kind of rambling and -- and</p> <p>24 you're going beyond the question I asked you.</p> <p>25 A. Sure. Go right ahead.</p>	<p style="text-align: right;">Page 413</p> <p>1 record. The time is 1:32. This is the</p> <p>2 beginning of tape 3.</p> <p>3</p> <p>4 M A R K G. K E N N Y, resumed having been</p> <p>5 previously duly sworn, was examined and testified</p> <p>6 further as follows:</p> <p>7</p> <p>8 EXAMINATION (Cont'd.)</p> <p>9 BY MR. KAPLAN:</p> <p>10 Q. All right. So we were just asking you</p> <p>11 about -- I was asking you about the preparation of</p> <p>12 your report and whether or not you got substantive</p> <p>13 input and direction from the Plaintiff's lawyers.</p> <p>14 A. Uh-huh.</p> <p>15 Q. And your answer to that?</p> <p>16 A. Absolutely no substantive information,</p> <p>17 direction, of any sort.</p> <p>18 Q. Okay. And I'm going to ask you</p> <p>19 whether you got substantive input and direction in</p> <p>20 the preparation of your report from Sal Romano?</p> <p>21 A. No, I did not.</p> <p>22 Q. Did not?</p> <p>23 A. Did not. The report is my report.</p> <p>24 Q. He had no input into it?</p> <p>25 A. We discussed it. Did he have input</p>

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<p style="text-align: right;">Page 414</p> <p>1 into the report? No. Because the report is mine, 2 has to be in my words. It has to be in my belief 3 system, and that's what is in this report. 4 Q. Did Mr. Romano give you direction as 5 to things that you should include in your report 6 that you didn't include in previous drafts? 7 A. Nothing, zero. 8 Q. And likewise as to the Plaintiff's 9 lawyers, did the Plaintiff's lawyers give you any 10 direction or input as to matters that should be 11 included in your final report that weren't included 12 in previous drafts? 13 A. No. 14 Q. And you're sure of that? 15 A. I'm sure of that. 16 Q. Let's just -- let's continue marching 17 through the documents that you were requested to 18 bring today and see what we have. You gave me the 19 correspondence and communication that you have had 20 with the Plaintiff's lawyers and other people with 21 whom you've been working, including Mr. Romano? 22 A. Correct. 23 Q. Number 3, all other documents prepared 24 by the attorneys for the plaintiffs and sent to the 25 witness?</p>	<p style="text-align: right;">Page 416</p> <p>1 gave you a CD of -- a copy of a CD with documents 2 that were sent to me. Those were primarily 3 plaintiff documents. I think all of them may have 4 begin with a P. You have that copy of that. 5 Q. You gave me two disks this morning. 6 A. Correct. 7 Q. Okay. And you're saying that any 8 documents that you received from plaintiffs other 9 than the e-mail correspondence would be on -- on 10 those two disks? 11 A. That's correct. 12 Q. Okay. 13 A. Do you want me to look, further look? 14 Q. Well, we're here today to take your 15 testimony and to make sure that I have in front of 16 me all the items that were requested so that I can 17 ask you questions. 18 A. (Hanging.) 19 Q. You're handing me a pile of documents 20 here that you are indicating would be responsive to 21 the request for documents prepared by attorneys for 22 the plaintiffs and sent to you? 23 A. No. Those are -- those are 24 communications. I didn't get anything of documents 25 that were prepared by them other than a contract --</p>
<p style="text-align: right;">Page 415</p> <p>1 A. Say that again, sir. 2 Q. All other documents prepared by the 3 attorneys for the plaintiffs and sent to the 4 witness? 5 A. Yes, I have -- I need to look through 6 that, but I have the e-mails. 7 Q. What do you need to look through? 8 A. I don't know if I threw them all in 9 there or not. 10 Q. Are they in here or are they not in 11 here? 12 A. Well, I don't know. I just want to 13 check. 14 Q. Okay. I have flagged some things -- 15 A. Are those all of the e-mails? If they 16 are all e-mails, then -- because I have a letter, a 17 contract letter, and I think that's pretty much it. 18 Would you like me to -- 19 Q. Just look and see whether other than 20 this file that has been marked as Exhibit 110, 21 whether there are any other documents that you 22 brought with you today that constitute other 23 documents prepared by the attorneys for the 24 plaintiffs and sent to you. 25 A. You mean -- does that include -- I</p>	<p style="text-align: right;">Page 417</p> <p>1 that's it. That's the only thing that I received. 2 MR. KAPLAN: Let's mark as Exhibit 111 3 this document. 4 (Whereupon, Exhibit 111, Chronology 5 from disks, was marked for identification as 6 of today's date.) 7 BY MR. KAPLAN: 8 Q. I will just say for the record that 9 this came from one of the disks that you gave me, 10 and the cover on that says, "Host name: 11 172.17.66.179." And then user name AMW. I don't 12 know what that means. And then job X10000012.XLS, 13 date and time, 2/16/11, 9:49. Was that -- oh, 14 that's us printing, okay. All right. At 9:49 this 15 morning. It was described as Motley timeline, 16 5/5/2010. 17 A. Okay. 18 Q. Does that ring a familiar note to you? 19 A. I have several versions of this 20 document. 21 Q. All right. Identify for the record 22 Exhibit 111. 23 A. Exhibit 111 does not have a title. It 24 is -- appears to be or it is, a chronology that I 25 made based upon documents as I saw them. So I tried</p>

30 (Pages 414 to 417)

<p style="text-align: right;">Page 418</p> <p>1 to understand the sequence of events.</p> <p>2 Q. Why does it say Motley timeline?</p> <p>3 A. Oh, why? Because it was associated</p> <p>4 with Motley, it had nothing to do with them. They</p> <p>5 did not originate this. They didn't even see it.</p> <p>6 Q. Okay. Mylan is not mentioned in</p> <p>7 Exhibit 111, is it?</p> <p>8 A. Mylan is not mentioned, that is</p> <p>9 correct.</p> <p>10 Q. From the group of documents that you</p> <p>11 just gave me, and I'm just going through them for</p> <p>12 the first time here. I'm going to mark this, but I</p> <p>13 want to read this to you and -- and I'm going to ask</p> <p>14 you about it. Something I just noted here is an</p> <p>15 e-mail from Sal Romano to Meghan Johnson Carter with</p> <p>16 a copy to SpyGlass, that's you, subject Re first</p> <p>17 draft, and it says, "Meg, Mark and I" -- you're</p> <p>18 Mark, right?</p> <p>19 A. Uh-huh.</p> <p>20 Q. "Mark and I were expecting to hear</p> <p>21 from you today with your edits. Mark will make the</p> <p>22 final corrections tomorrow. Can he e-mail you a</p> <p>23 copy and send the signed copy at a later date?</p> <p>24 Thanks, Sal."</p> <p>25 A. Right. That had to do with the --</p>	<p style="text-align: right;">Page 420</p> <p>1 Q. Okay. So the only thing that -- that</p> <p>2 the Plaintiff's lawyers did was check your spelling?</p> <p>3 A. Yes, basically.</p> <p>4 Q. And that's what you were waiting to</p> <p>5 hear from them with regard to your spelling?</p> <p>6 A. No. That is not -- what I said is not</p> <p>7 correct with Meghan. With another conversation, the</p> <p>8 wording that I had used, they -- they said -- you</p> <p>9 have to ask yourself a question, whether or not --</p> <p>10 and I'd have to read the statement, but basically</p> <p>11 it's -- let me read it. And this is not part of my</p> <p>12 vocabulary.</p> <p>13 Q. What are you referring to?</p> <p>14 A. It is my -- looking in the expert</p> <p>15 witness, I repeated this phrase many times, looking</p> <p>16 at page 35, the second paragraph (indicating).</p> <p>17 Q. With all due respect, let's go back to</p> <p>18 my question, because I think you kind of brushed</p> <p>19 over it. Let's just repeat the question and then --</p> <p>20 and then let me have your response.</p> <p>21 MS. CARTER: I think he's trying to</p> <p>22 answer it though.</p> <p>23 A. I'm trying to.</p> <p>24 MR. KAPLAN: Okay. Well, let's see.</p> <p>25 Ask him the question again, and let's see.</p>
<p style="text-align: right;">Page 419</p> <p>1 with the documents that you've seen, which you have</p> <p>2 copies of. So he's talking about the document that</p> <p>3 I am creating. See, Sal originally was --</p> <p>4 Q. Wait, wait, wait.</p> <p>5 A. Sure. Go ahead.</p> <p>6 Q. There's no question pending right now.</p> <p>7 Okay. Again, with all due respect, you -- you have</p> <p>8 to just slow down and answer my question, just my</p> <p>9 question, okay?</p> <p>10 A. I understand.</p> <p>11 Q. Okay. So Sal says on June 14th, the</p> <p>12 day before you signed the report that you and he</p> <p>13 were expecting to hear from Meg, who is sitting here</p> <p>14 today, Meg -- Meghan Carter, the Plaintiff's</p> <p>15 attorney, to get her edits to your report, right?</p> <p>16 A. That's correct.</p> <p>17 Q. So does that now refresh your</p> <p>18 recollection and change your testimony that you gave</p> <p>19 earlier that you did not get input and direction</p> <p>20 from the plaintiff's attorney as to the content of</p> <p>21 your report?</p> <p>22 A. No. I explained earlier that Meghan</p> <p>23 gave me spelling corrections. There was no content</p> <p>24 change as a result of our -- our working together,</p> <p>25 none, zero.</p>	<p style="text-align: right;">Page 421</p> <p>1 (Record read.)</p> <p>2 A. It does not change what I said.</p> <p>3 BY MR. KAPLAN:</p> <p>4 Q. Okay. That's the only question I</p> <p>5 asked you.</p> <p>6 A. Okay.</p> <p>7 Q. And did you tell me that Russell Somma</p> <p>8 was not involved in the --</p> <p>9 A. Russell Somma was -- I was not</p> <p>10 involved with Russell, the work that he did.</p> <p>11 Q. Was he involved with you?</p> <p>12 A. Only through an introduction.</p> <p>13 Q. Okay. Well -- and -- and I'm happy to</p> <p>14 show you this too, but again, in this pile of</p> <p>15 documents that you just handed me, I see an e-mail</p> <p>16 from Russell Somma dated May 14, 2010. That's a</p> <p>17 month before you submit your final report of</p> <p>18 June 15, 2010?</p> <p>19 A. Right.</p> <p>20 Q. To SpyGlass Group, that's you, and to</p> <p>21 Sal Romano.</p> <p>22 A. Okay.</p> <p>23 Q. Re meeting with Motley Rice and Pete</p> <p>24 Miller. Motley Rice is Meghan, right?</p> <p>25 A. Yes. That was -- that was a -- over</p>

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<p style="text-align: right;">Page 422</p> <p>1 the phone, I believe.</p> <p>2 Q. And the e-mail says Mark --</p> <p>3 A. I was never with him.</p> <p>4 Q. "Mark, Sal, let's do a TC," telephone</p> <p>5 call, "Saturday, easier for everyone I think. Plan</p> <p>6 for 9 a.m. for a half hour, call in." And it gives</p> <p>7 the number. "Speak with you both then, Russ."</p> <p>8 A. And it had -- yes. I don't remember</p> <p>9 the exact conversation, but I do remember that we</p> <p>10 talked over the phone. Actually, I'm not sure that</p> <p>11 actually happened, but it probably did.</p> <p>12 Q. And so you had Russell Somma's input</p> <p>13 and direction in shaping the expert report of</p> <p>14 June 15, 2010?</p> <p>15 A. Absolutely nothing. He had no input.</p> <p>16 Q. So when Russell Somma says to you in</p> <p>17 his e-mail of May 12, 2010, "Sal, Mark, met with</p> <p>18 these folks until nine last night. I requested some</p> <p>19 further information and generally reviewed what the</p> <p>20 expert report will be speaking to. We need to</p> <p>21 coordinate our efforts for sure. Let me know when</p> <p>22 you guys want to talk."</p> <p>23 A. Right.</p> <p>24 Q. "We can set up regular meetings for</p> <p>25 review of progress."</p>	<p style="text-align: right;">Page 424</p> <p>1 were. I wanted to see if he knew what he was</p> <p>2 talking about.</p> <p>3 Q. Well, when he says on May 14 that he</p> <p>4 requested some further information --</p> <p>5 A. I don't know what -- the information I</p> <p>6 am sure had to do with the scope of his review as</p> <p>7 opposed to our review.</p> <p>8 Q. And then he says "and generally</p> <p>9 reviewed what the expert report will be speaking</p> <p>10 to." What do you mean?</p> <p>11 A. Right. In other words, I know</p> <p>12 exactly. That would -- would take -- I knew nothing</p> <p>13 about the technology of tableting. I didn't want to</p> <p>14 offer an opinion at all, zero, I didn't even want to</p> <p>15 touch it.</p> <p>16 Q. And did you?</p> <p>17 A. No, of course not.</p> <p>18 Q. Okay.</p> <p>19 A. But he was. I wanted to make sure</p> <p>20 that he's covering that and I'm covering this. And</p> <p>21 I don't want him delving in an area that he's not an</p> <p>22 expert in, okay.</p> <p>23 Q. And so when Russell Somma --</p> <p>24 A. So we tried -- we tried to set up a</p> <p>25 line.</p>
<p style="text-align: right;">Page 423</p> <p>1 A. Right.</p> <p>2 Q. What do you think he meant?</p> <p>3 A. Originally, we thought that our</p> <p>4 approach was going to be he takes a certain portion</p> <p>5 of the operations, and then we don't duplicate that</p> <p>6 work and do the rest of it. As it turned out, we</p> <p>7 had no collaboration whatsoever, zero. It was -- it</p> <p>8 was a theoretical model, if you will, that we went</p> <p>9 into this that, you know, you take the left, I take</p> <p>10 the center and the right. And -- and as it turned</p> <p>11 out, we became -- since he was not part of the</p> <p>12 SpyGlass Group, I did not want to assume any</p> <p>13 liability or whatever for what he did, so we became</p> <p>14 100 percent independent at that point.</p> <p>15 Q. So he worked with you up until May 14,</p> <p>16 2010, and then you cut him loose?</p> <p>17 A. No. We had -- originally, we thought</p> <p>18 that he would -- no. To answer your question, no.</p> <p>19 Q. Did he work with you up until May 14</p> <p>20 of 2010?</p> <p>21 A. Nothing, zero. I had one -- I had one</p> <p>22 interview with him up in Chester or something like</p> <p>23 that.</p> <p>24 Q. What was the interview about?</p> <p>25 A. I wanted to see what his credentials</p>	<p style="text-align: right;">Page 425</p> <p>1 Q. So when Russell Somma says to you on</p> <p>2 this is May 12, I think I said May 14th. It's May</p> <p>3 12, 2010. We need to coordinate our efforts?</p> <p>4 A. Yes, that's it.</p> <p>5 Q. What does that mean to you?</p> <p>6 A. It meant using a vin (phonetic)</p> <p>7 diagram, who's covering what.</p> <p>8 Q. And what did you decide?</p> <p>9 A. We decided that he covers anything to</p> <p>10 do with tableting and we would cover everything</p> <p>11 else.</p> <p>12 Q. Is Denise your wife?</p> <p>13 A. Yes, she is.</p> <p>14 Q. And on April 26, 2010, I see an e-mail</p> <p>15 here from SpyGlass Group to Meghan Johnson Carter,</p> <p>16 Re SpyGlass billing, as follows: "Hi, Meghan, this</p> <p>17 is to confirm 340 per her for Russ and 430 per hour</p> <p>18 for SpyGlass."</p> <p>19 A. Correct.</p> <p>20 Q. What does that mean?</p> <p>21 A. That means originally when we talked</p> <p>22 to Motley, we -- we did it under the understanding</p> <p>23 that he would be part of our consulting group. Much</p> <p>24 like all other consulting groups, you bring in</p> <p>25 experts as is necessary. I had a discussion with</p>

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<p style="text-align: right;">Page 426</p> <p>1 him, and I was feeling more and more uncomfortable 2 about the scenario, so -- but I explained to him, I 3 said there is a loss on our part if you feel that 4 Russ can do the work. So we negotiated an 5 additional \$30 per. So Russ would do his own thing 6 and we would do our own thing. So we increased our 7 hourly rate \$30. 8 Q. Sounds like Russ was part of the 9 group? 10 A. Russ was not part of the group. 11 That's the reason why we got -- we did the split 12 that way. He was not part of the group. He never 13 billed. He's not part of our group in any manner, 14 there is no contract, there's not even an implicit 15 contract, nothing. 16 Q. Why -- why do you think your wife told 17 Meghan what his hourly rate was? 18 A. Because -- because originally, the 19 concept was that he would be part of the SpyGlass 20 Group. 21 Q. Well, this is April 26, 2010. 22 A. I don't care what date -- the date is 23 immaterial to me. I am explaining to you what the 24 arrangements were. 25 Q. Your initial draft report was</p>	<p style="text-align: right;">Page 428</p> <p>1 You see that? 2 A. Now I understand some of the lack of 3 understanding. 4 Q. Do you see January 1 -- 5 A. I could have put -- I could have put 6 January 1949. It's meaningless. This is a place 7 keeper. 8 Q. Okay. On your -- on your draft report 9 that you have in your hand right now -- 10 A. On every report, I don't put the date 11 until I was ready in the June whatever time frame. 12 That's -- that's when I started dating it because it 13 started making sense to date it. 14 Q. Did you start dating it January 1, 15 2010 after January 1, 2010? 16 A. You're going to have to ask that 17 again, please. 18 Q. Let's go back. I'm trying to figure 19 out here why it is in April 26 -- on April 26, 2010, 20 your wife, who does the business end of the SpyGlass 21 deal, writes to Meghan saying Russ' rate is 340 an 22 hour. And all I'm trying to do is establish that 23 looks like Russ was part of the collaborative effort 24 that went into this report? 25 A. That couldn't be more -- that couldn't</p>
<p style="text-align: right;">Page 427</p> <p>1 January 1, 2010. 2 A. It doesn't -- okay. 3 Q. Right? 4 A. If it is, yeah, I gave you the report. 5 Q. I'll guarantee it is, and it's right 6 in front of you. 7 A. Oh, no, no. This is not January 2010. 8 This is a place keeper. This has nothing to do with 9 anything. 10 Q. So you're looking at your initial 11 draft report, and it's dated January 1, 2010? 12 A. It's meaningless. That's a place 13 keeper. 14 Q. What do you mean by that? 15 A. I put January -- a place keeper, it's 16 so that I don't forget to put a date. It's not the 17 date of the report, has nothing to do with -- 18 Q. What is the date of the report? 19 A. I don't know. You'd have to -- I 20 don't know what the date of the report is. 21 Q. Well, look at it and tell me. 22 A. I can't -- unless I wrote it down, I 23 can't tell you. 24 Q. Okay. I -- the only thing I see in 25 writing on your draft report is January 1, 2010.</p>	<p style="text-align: right;">Page 429</p> <p>1 be more false. 2 Q. Okay. And I'm also looking at your 3 draft report, and you look at it too, and you tell 4 the jury what date is on there? 5 A. It says January 2010, but it is a -- 6 Q. Just a minute. What date is shown on 7 that report? 8 A. Excuse me, sir. January 1st, 2010. 9 Q. All right. That's my -- that's all I 10 want you to -- 11 A. Okay. 12 Q. I see another e-mail among the 13 documents that you gave me here from Sal Romano to 14 Meghan Johnson Carter with copies to Sandy Summers. 15 Who is that? 16 A. I don't recall. 17 Q. Fred Thompson, you know Mr. Thompson 18 from Motley, right? 19 A. Well, I talked to him on the phone 20 once. 21 Q. And the subject is, "need some files." 22 Sal says: March 17, 2010: "Meg, I think we had a 23 good meeting with you and Pete Miller on the phone 24 on Monday. We have a better idea of what you want 25 from us, and we believe we can deliver it to you to</p>

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<p style="text-align: right;">Page 430</p> <p>1 your satisfaction." 2 A. In other words, a complete report. 3 Q. What "better idea" did you get of what 4 they, the Plaintiff's lawyers, wanted from you? 5 A. I -- I don't know that I can answer 6 that. I don't recall. 7 Q. What is it that you could deliver to 8 the Plaintiff's lawyers to their satisfaction? 9 A. A comprehensive report because without 10 some direction, having no experience, zero, in this, 11 you know, you're dealing in somewhat of a void. 12 Q. So you relied upon the plaintiff's 13 lawyers to tell you what they wanted in your report? 14 A. What their -- what the objective was. 15 What is the objective, which later appeared in my 16 report. 17 Q. When was it that you were first 18 contacted by the plaintiff's lawyers? 19 A. I don't have the date, but the e-mail 20 trail would -- would speak to that. 21 Q. How much have you billed the 22 plaintiff's lawyers to date for the work that you 23 have done? 24 A. Approximately \$90,000. 25 Q. And how about Sal Romano?</p>	<p style="text-align: right;">Page 432</p> <p>1 right? 2 A. I'd have to look at the numbers. 3 Q. Is that approximately, correct? 4 A. I'm going to assume that it is, it was 5 a lot -- lots. 6 Q. You only looked at three batch 7 records, didn't you? 8 A. Those were the only ones that I had 9 available, the only ones that were part of the data 10 base. You know, you get what you get. There was a 11 lot of information everybody wants. 12 MR. KAPLAN: I'm going to mark this as 13 Exhibit 112. 14 (Whereupon, Exhibit 112, E-mail, was 15 marked for identification as of today's 16 date.) 17 BY MR. KAPLAN: 18 Q. I'm handing you Exhibit 112. First, 19 look at the e-mail from Sal Romano to you dated 20 February 24 -- I mean from you to Sal, dated 21 February 24, 2010. You say as follows: "Sal, the 22 actual batch records are extremely important. Do 23 you want me to request the information? Mark." 24 Then above that is an e-mail from Sal dated 25 February 24 to Meghan Johnson Carter saying, "Mark</p>
<p style="text-align: right;">Page 431</p> <p>1 A. I'm going to guess, I don't know 2 exactly, but I'm going to guess 20,000. 3 Q. And how much time do you have that is 4 yet unbilled? 5 A. How much time, 14 yesterday, four and 6 a half, and today. 7 Q. That's it? 8 A. That's it. 9 Q. Everything else has been billed? 10 A. Everything else is billed, paid in 11 full. 12 Q. So you billed approximately 90,000 or 13 exactly 90,000 or 100,000? 14 A. Within -- I have the numbers over 15 there, but it's 90,000. I have the records for you. 16 Q. Okay. Well, we'll get to that. 17 You -- you and Sal agreed that the batch records 18 would be critical for you to review? 19 A. We wanted to see a lot of records, 20 correct. 21 Q. You and Sal agreed that the batch 22 records would be critical for you to review, 23 correct? 24 A. Yes. 25 Q. 152 batches were recalled; is that</p>	<p style="text-align: right;">Page 433</p> <p>1 and I believe the batch records will be critical for 2 us to review." 3 Do you see that? 4 A. Yes. 5 Q. "How many batches are recalled? Do 6 you have all the batch records as PDF files? We 7 have lots to read now, but I think we'll have to 8 look at the batch records soon, right?" 9 A. Yes, that's what it says. 10 Q. Did you? 11 A. Did I see additional batch records 12 other than those that I have either here or in the 13 references, no. 14 Q. You looked at only three batch 15 records? 16 A. Three -- I believe that's correct, 17 three or four. 18 Q. You looked at three batch records, 19 didn't you? 20 A. I would have to add them up, but it's 21 at least three. Yeah, but let's say three. 22 Q. That was your sworn testimony on June 23 29, 2010. Are you changing that testimony? 24 A. No, I'm not. 25 Q. All right. You looked at three batch</p>

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<p style="text-align: right;">Page 434</p> <p>1 records.</p> <p>2 A. Okay.</p> <p>3 Q. Meghan told you that there are</p> <p>4 approximately 170 plus batches for Digoxin, right?</p> <p>5 A. Yes.</p> <p>6 Q. And you looked at three?</p> <p>7 A. I looked at three.</p> <p>8 Q. But they were critical?</p> <p>9 A. They were critical if you wanted to</p> <p>10 find more exceptions, more issues.</p> <p>11 Q. Doesn't say if we wanted to find more</p> <p>12 issues. You say they're critical.</p> <p>13 A. That's what I said, and I'm telling</p> <p>14 you what that means.</p> <p>15 Q. And you stand by that, don't you?</p> <p>16 A. What do I stand by, that I wrote that?</p> <p>17 Q. Those are your words, aren't they?</p> <p>18 A. I wrote that in an e-mail, that is</p> <p>19 correct.</p> <p>20 Q. Those are your words, are they not?</p> <p>21 A. Those are my words.</p> <p>22 Q. There were a number of phone</p> <p>23 conferences with Russell Somma, weren't there?</p> <p>24 A. We talked a couple of times. I don't</p> <p>25 know the number.</p>	<p style="text-align: right;">Page 436</p> <p>1 recommendation that he knew -- his expertise, and</p> <p>2 therefore, I wanted to interview him to see how</p> <p>3 practical, was he a theoretician or did he know what</p> <p>4 he was talking about.</p> <p>5 Q. Did he disagree with the conclusions</p> <p>6 that you came to?</p> <p>7 A. He never saw any conclusions that I</p> <p>8 came to, not a single piece of paper.</p> <p>9 Q. Never heard you say what your</p> <p>10 conclusions were?</p> <p>11 A. No, he did not.</p> <p>12 Q. How about Sal's conclusions?</p> <p>13 A. You have to talk to Sal, but I don't</p> <p>14 believe that he talked to Sal outside of</p> <p>15 conversations that we had. I'm almost positive.</p> <p>16 Q. Who is Denise DeLongas?</p> <p>17 A. That's my wife.</p> <p>18 Q. Oh, okay. Sorry.</p> <p>19 A. Wonderful lady.</p> <p>20 Q. I'm sure.</p> <p>21 A. Best of the best. Can you put that</p> <p>22 down in the record?</p> <p>23 Q. You just did.</p> <p>24 A. Excellent.</p> <p>25 Q. You just did, and you know what, it</p>
<p style="text-align: right;">Page 435</p> <p>1 Q. Well, I'm looking at another e-mail</p> <p>2 here dated March 30, 2010 from Russell Somma to you,</p> <p>3 to Meghan Johnson Carter, to Pete Miller, and to Sal</p> <p>4 Romano with a copy to Sandy Summers saying, "Mark,</p> <p>5 Meghan, Sal, and Pete, I will be available for a</p> <p>6 telephone conference on Monday at 9 a.m. and hope</p> <p>7 this accommodates everyone's schedule. Sorry about</p> <p>8 the delay as I'm traveling right now."</p> <p>9 A. Okay.</p> <p>10 Q. Does that refresh your recollection</p> <p>11 that --</p> <p>12 A. I don't remember that meeting actually</p> <p>13 being held, but I'm going to assume it probably was.</p> <p>14 It was an unmemorable meeting.</p> <p>15 Q. Now, Russell Somma has a bachelor of</p> <p>16 science in pharmacy, doesn't he?</p> <p>17 A. If his résumé says that.</p> <p>18 Q. And a masters in science and</p> <p>19 pharmaceutical science?</p> <p>20 A. If his resume says that.</p> <p>21 Q. And a PhD in pharmaceutical science?</p> <p>22 A. If his resume says that.</p> <p>23 Q. So you -- you had no idea what his</p> <p>24 qualifications were?</p> <p>25 A. I read that and I received</p>	<p style="text-align: right;">Page 437</p> <p>1 was Valentine's day Monday, but I think you ought to</p> <p>2 show it to her now and --</p> <p>3 A. We don't go there.</p> <p>4 Q. Okay. On March 23, 2010, you sent an</p> <p>5 e-mail to Meghan Johnson Carter with copies to Fred</p> <p>6 Thompson and Pete Miller saying that you would like</p> <p>7 them to review Russ Somma's qualifications. And you</p> <p>8 said, "I recommend you consider Russ Somma as part</p> <p>9 of the evaluation team."</p> <p>10 A. Right.</p> <p>11 Q. "Russ has worked very closely with one</p> <p>12 of the SpyGlass Group's core members. His</p> <p>13 credentials are outstanding."</p> <p>14 A. Right.</p> <p>15 Q. That's what you -- that's what you</p> <p>16 told the plaintiff's lawyers, and that's what you</p> <p>17 recommended?</p> <p>18 A. Yes. That's correct. But his</p> <p>19 credentials means Bob Sierra's credentials.</p> <p>20 Q. Whose credentials?</p> <p>21 A. Bob Serra, the gentleman that I talked</p> <p>22 to about finding an expert. He said that this --</p> <p>23 that this guy's the best. I said great. Let's</p> <p>24 talk.</p> <p>25 Q. And you recommended him?</p>

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<p style="text-align: right;">Page 438</p> <p>1 A. I recommended that they consider him, 2 that's what I said. I can't -- I didn't recommend 3 him because I never worked with him, but I talked to 4 him, he's a bright guy. He's got great experience, 5 he knows his stuff. 6 Q. He worked with somebody in the 7 SpyGlass Group? 8 A. Bob Serra, apparently they have a long 9 term relationship. I never heard the man's name 10 before, nor did Sal. 11 Q. As late as June 4, 2010, you and Sal 12 were meeting with the Plaintiff's lawyers? 13 A. Were meeting what? 14 Q. With the Plaintiff's lawyers? 15 A. The Plaintiff's lawyers? On the 16 phone, we probably discussed things. 17 Q. How about early Friday morning, 18 June 4th, at the Newark airport? 19 A. We met. 20 Q. That wasn't on the phone, that was in 21 person? 22 A. That was in person, correct. 23 Q. You -- you met in a hotel conference 24 room there? 25 A. Yes.</p>	<p style="text-align: right;">Page 440</p> <p>1 A. I'm saying some of the work he looked 2 at and the work he did was redundant. 3 Q. So when -- when Sal Romano says on 4 May 24, 2010 in an e-mail to Meghan Johnson Carter, 5 "Meg, let's talk about strategy for a moment." 6 A. I'm sorry. You have to repeat that. 7 Can I read these? 8 Q. Just -- just try to answer my 9 questions, okay. So when -- so when Sal Romano says 10 to Meghan Johnson Carter on May 24, 2010, "Meg, 11 let's talk about strategy for a moment." And goes 12 on to say, "Mark and I will both sign our SpyGlass 13 report." 14 A. Right. That was originally the 15 concept. 16 Q. Well, it was the concept through the 17 meeting at the Newark airport hotel conference room 18 on June 4, 2010? 19 A. Okay. 20 Q. Eleven days later, you submitted the 21 report? 22 A. Right. 23 Q. You had had a prior meeting, a meeting 24 prior to May 24, 2010 with the plaintiff's lawyers, 25 didn't you?</p>
<p style="text-align: right;">Page 439</p> <p>1 Q. Did you forget that? 2 A. Yes. 3 Q. And you met to discuss the report? 4 A. That's correct. 5 Q. Which Sal told Meghan Johnson Carter 6 on May 28 was in good shape? 7 A. Okay. 8 Q. And it's in its fourth draft; is that 9 right? 10 A. If that's what it says. 11 Q. He says we. Doesn't say Mark. 12 A. That's correct. He was proofing it. 13 Q. He says, "We are planning to have it 14 done next week." 15 A. That's correct. If it says that, that 16 is correct. 17 Q. Sounds like he's had a lot of input on 18 this report? 19 A. He's had no input to the context -- 20 content of that report. None. 21 Q. Well, what was he billing all of that 22 time for? 23 A. His review time. It was redundant. 24 Q. So you're saying Sal Romano is 25 redundant?</p>	<p style="text-align: right;">Page 441</p> <p>1 A. A meeting where? We talked on the 2 phone a few times. 3 Q. Sal goes on to say in this e-mail of 4 May 24, 2010 to Meghan Johnson Carter, "So if I 5 understood you at our meeting with Pete, you will 6 want to depose both Mark and me." 7 A. Right. We met with them twice, one in 8 New York City, one in Newark, and you're referring 9 to both of those meetings. On and off he referred 10 to them. 11 Q. He goes on to say on May 24, 2010, 12 "Then should we be doing this on the same day? If 13 that is the case, then I can't make it on June 24 or 14 25. I do have free time June 16 and 23. I don't 15 know about Mark." The plan was that Sal was going 16 to sign this report along with you? 17 A. That's correct. 18 Q. And that Sal was going to be deposed 19 as an expert as well? 20 A. I assume that is correct. Well, it 21 depends -- 22 Q. What -- what changed that plan? 23 A. He couldn't -- he couldn't do it. He 24 didn't have the -- his schedule would not allow it. 25 Q. What?</p>

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Mark Kenny, Volume II

Videotaped

February 16, 2011

<p style="text-align: right;">Page 442</p> <p>1 A. His schedule would not allow it.</p> <p>2 Q. Well, he says -- he gives dates when</p> <p>3 he is available.</p> <p>4 A. Whatever. I don't know. He talked, I</p> <p>5 assume with them, and the dates, including science</p> <p>6 day, including some trial date. There is no way he</p> <p>7 could possibly make it, so he felt that he couldn't</p> <p>8 be -- participate any further.</p> <p>9 Q. I do have free time, he says, June 16</p> <p>10 and 23. That's what he says?</p> <p>11 A. I go by what I just said, he cannot</p> <p>12 give a full commitment, as I could. I can give a</p> <p>13 full commitment.</p> <p>14 Q. So let me understand this now. Sal</p> <p>15 Romano contributed to the report and to the opinions</p> <p>16 that were expressed in that report, but he was</p> <p>17 pulled off to avoid his deposition?</p> <p>18 A. That is not correct. That report is</p> <p>19 my report. Okay. Every bit of it is my report.</p> <p>20 Sal acted as a consultant to me of which I was the</p> <p>21 one with the experience, not Sal.</p> <p>22 Q. Sal, in another e-mail, says, "It was</p> <p>23 a pleasure meeting" -- to Meg, "It was a pleasure</p> <p>24 meeting you and Pete in NYC."</p> <p>25 A. Yeah.</p>	<p style="text-align: right;">Page 444</p> <p>1 BY MR. KAPLAN:</p> <p>2 Q. -- 2010 but didn't sign that report?</p> <p>3 A. It sounds like a rhetorical question.</p> <p>4 I don't understand your question.</p> <p>5 Q. What don't you understand?</p> <p>6 A. Well, I didn't -- it sounds like you</p> <p>7 made a question and then answered it.</p> <p>8 Q. I'd love to hear what Sal Romano has</p> <p>9 to say, but he was pulled off the report, wasn't he?</p> <p>10 A. He pulled himself off of it because of</p> <p>11 a commitment.</p> <p>12 Q. When was the last time you talked to</p> <p>13 Sal Romano about the report?</p> <p>14 A. The report? It was before it was</p> <p>15 issued. I didn't talk to him since about this</p> <p>16 subject. I've talked to him, but not about this.</p> <p>17 He had no interest in it.</p> <p>18 Q. Okay. Number four, all documents</p> <p>19 including documents and deposition transcripts which</p> <p>20 refer or relate to DIGITEK that the witness received</p> <p>21 from any source. You brought all of that?</p> <p>22 A. Yes.</p> <p>23 Q. Where is it?</p> <p>24 A. You -- you have everything.</p> <p>25 Q. Where?</p>
<p style="text-align: right;">Page 443</p> <p>1 Q. That was a meeting in the city?</p> <p>2 A. Right.</p> <p>3 Q. "I'm available pretty much from</p> <p>4 June 16 to 23 for a deposition if they want me."</p> <p>5 A. Right. But he couldn't commit beyond</p> <p>6 that, and his fear was that he would have to</p> <p>7 interrupt all of his business and personal plans to</p> <p>8 continue this -- this project.</p> <p>9 Q. You said something about -- well, he</p> <p>10 also says, "I will be available for the trial dates</p> <p>11 if needed."</p> <p>12 A. I can't tell you what that says. I</p> <p>13 can tell you that he felt he could not commit to the</p> <p>14 time and bowed out. It could say whatever it says,</p> <p>15 I don't know.</p> <p>16 Q. Well, these aren't my words, these are</p> <p>17 Sal Romano's words.</p> <p>18 A. You have to talk to Sal as to why he</p> <p>19 felt he could not do it.</p> <p>20 Q. And that's what I'm wondering, how in</p> <p>21 the world am I going to be talking to Sal when he</p> <p>22 apparently has a role in the report that was</p> <p>23 rendered on June 15 --</p> <p>24 MS. CARTER: Objection.</p> <p>25</p>	<p style="text-align: right;">Page 445</p> <p>1 A. Read it again, just to make sure.</p> <p>2 Q. All documents including documents and</p> <p>3 deposition transcripts which refer or relate to</p> <p>4 DIGITEK that the witness received from any source?</p> <p>5 A. Deposition? I received nothing.</p> <p>6 Q. No, no. You're focusing on</p> <p>7 depositions.</p> <p>8 A. I need to read that, sir.</p> <p>9 MR. KAPLAN: Okay. Can you put that</p> <p>10 in front of him, Meghan?</p> <p>11 (Off-the-record discussion.)</p> <p>12 Here you are. We'll just mark this as</p> <p>13 Exhibit 113.</p> <p>14 (Whereupon, Exhibit 113, Amended</p> <p>15 notice for video deposition, was marked for</p> <p>16 identification as of today's date.)</p> <p>17 BY MR. KAPLAN:</p> <p>18 Q. Just for the record, Exhibit 113 that</p> <p>19 I've put in front of you is the document that we've</p> <p>20 been talking about which is the amended notice for</p> <p>21 your video deposition here today requesting that you</p> <p>22 bring categories of documents that are listed. You</p> <p>23 understand that, right?</p> <p>24 A. Oh, certainly.</p> <p>25 Q. And you saw it before you came here</p>

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<p style="text-align: right;">Page 446</p> <p>1 today?</p> <p>2 A. Yes, I did.</p> <p>3 Q. And you have complied with the</p> <p>4 request?</p> <p>5 A. That's correct.</p> <p>6 Q. And we're going through to make sure</p> <p>7 now that -- that you did and that I have everything</p> <p>8 and that Mr. Anderton has everything. Okay?</p> <p>9 A. Yes.</p> <p>10 Q. All right. So we're at number four.</p> <p>11 All documents including documents and deposition</p> <p>12 transcripts which refer or relate to DIGITEK that</p> <p>13 the witness received from any source.</p> <p>14 A. The only depositions I have are the</p> <p>15 ones that we've talked about, and I have my own</p> <p>16 deposition. That's it.</p> <p>17 Q. Again, with all due respect, as I said</p> <p>18 before, you're focusing on the word deposition.</p> <p>19 Look before that. All documents including --</p> <p>20 A. This is -- this is everything that is</p> <p>21 here falls underneath that. There is --</p> <p>22 Q. So when you say "everything that is</p> <p>23 here," and you point to something on the ground?</p> <p>24 A. I point to three huge volumes of paper</p> <p>25 that I've collected and kept together so that when</p>	<p style="text-align: right;">Page 448</p> <p>1 (Whereupon, Exhibits 114-139,</p> <p>2 documents brought by the Witness in three</p> <p>3 milk crates, were marked for identification</p> <p>4 as of today's date.)</p> <p>5 THE VIDEOGRAPHER: We're back on the</p> <p>6 record. The time is 2:35.</p> <p>7 BY MR. KAPLAN:</p> <p>8 Q. We went off the record so that we</p> <p>9 could mark as exhibits the documents that you</p> <p>10 brought with you here today. The court reporter has</p> <p>11 marked those documents as exhibits 114 through 139.</p> <p>12 Does that include everything that you brought with</p> <p>13 you?</p> <p>14 A. Yes.</p> <p>15 Q. All right. And we're going through</p> <p>16 the list of documents that you were requested to</p> <p>17 bring pursuant to the amended notice duces tecum for</p> <p>18 your deposition. We were on number four, all</p> <p>19 documents including documents and deposition</p> <p>20 transcripts which refer or relate to DIGITEK that</p> <p>21 the witness received from any source. And those</p> <p>22 documents are among exhibits 114 through 139, right?</p> <p>23 A. All of them are among that, yes.</p> <p>24 Q. Okay. Number 5 asks for all retainer</p> <p>25 agreements or other agreements under which the</p>
<p style="text-align: right;">Page 447</p> <p>1 this is asked, I can hand it over.</p> <p>2 Q. That's fine. And I just -- all I want</p> <p>3 to do is have that.</p> <p>4 A. Yes. You have it all. You started</p> <p>5 looking at it, sir. I'm sorry. I'm not trying to</p> <p>6 be argumentative.</p> <p>7 Q. With -- with -- with all due respect,</p> <p>8 I'm just trying to identify what is responsive to</p> <p>9 these requests.</p> <p>10 A. I understand. I think that's fair.</p> <p>11 Q. All right. Thank you. And so I want</p> <p>12 to mark all of the documents that you pointed to</p> <p>13 over there that you say are crates or whatever. I</p> <p>14 know you -- I know you came up with some --</p> <p>15 A. Crates is a better word.</p> <p>16 Q. Okay. Notebooks. So we can mark</p> <p>17 those now. Let's -- let's just do that.</p> <p>18 MR. KAPLAN: In fact, we can take a</p> <p>19 break and -- and we'll mark them. We'll</p> <p>20 just take a minute or two. I just want to</p> <p>21 make sure we have those marked, they are</p> <p>22 part of the record.</p> <p>23 THE VIDEOGRAPHER: We're off the</p> <p>24 record. The time is 2:19.</p> <p>25 (recess taken.)</p>	<p style="text-align: right;">Page 449</p> <p>1 witness has been or will be paid for work related to</p> <p>2 the DIGITEK litigation?</p> <p>3 A. Okay. This is a portion of it.</p> <p>4 There's another folder in there. Let me give you a</p> <p>5 portion of it. Here it is. Here are all of this</p> <p>6 (handing). That -- that's going to be duplicates,</p> <p>7 by the way. This should have everything.</p> <p>8 Q. By the way, when your deposition was</p> <p>9 taken on June 29, 2010, you said that 50 percent of</p> <p>10 the work that you were doing was for the plaintiff's</p> <p>11 lawyers in this litigation, 50 percent of your total</p> <p>12 work?</p> <p>13 A. Perhaps at that period of time. It's</p> <p>14 not -- it is approximately about over 30, less than</p> <p>15 40 percent. Because I grossed almost \$400,000, so</p> <p>16 90, at that point, would be 25, so it's less. But I</p> <p>17 was getting paid more and more by the end of the</p> <p>18 year. I did a lot of assignments.</p> <p>19 Q. So you're saying in 2010, you grossed</p> <p>20 \$400,000?</p> <p>21 A. Almost, 380,000.</p> <p>22 Q. And that your total bills to the</p> <p>23 plaintiff's lawyers were?</p> <p>24 A. Approximately 90.</p> <p>25 Q. So about 25 percent of your income?</p>

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<p style="text-align: right;">Page 450</p> <p>1 A. Yeah. Right.</p> <p>2 Q. In 2010 --</p> <p>3 A. Correct.</p> <p>4 Q. -- was attributable to work that you</p> <p>5 did for the Plaintiff's lawyers in this litigation?</p> <p>6 A. That's correct.</p> <p>7 Q. But you -- you made a distinction in</p> <p>8 your previous deposition as to the percentage of</p> <p>9 your income and the amount of your work related to</p> <p>10 this litigation. You said 50 percent of your work</p> <p>11 was related to the DIGITEK litigation?</p> <p>12 A. I believe you talked to me up to that</p> <p>13 point, you said up to that point. Then I said, well</p> <p>14 I have all of these promissory notes, I'm going to</p> <p>15 get contracts, I've got to get paid another 40,000,</p> <p>16 and you said no, up to that point. And that's what</p> <p>17 I answered.</p> <p>18 Q. Okay. Up to June 29, 2010?</p> <p>19 A. Yes, that was my guess. But I also</p> <p>20 told you I didn't know, and I don't pay attention to</p> <p>21 it.</p> <p>22 Q. Got you. I do note here on this</p> <p>23 notebook that you gave me which has been marked as</p> <p>24 Exhibit 135 which has the label "DIGITEK Motley Rice</p> <p>25 attorneys at law." Is that from your shop, from</p>	<p style="text-align: right;">Page 452</p> <p>1 Q. Okay. The first page in this notebook</p> <p>2 marked Exhibit 135 is a note from your wife, Denise,</p> <p>3 to Meghan Johnson Carter, a message dated -- faxed</p> <p>4 on May 15, 2010, one month before you submitted your</p> <p>5 report saying, "Hi, Meghan, time sheets for Mark</p> <p>6 Kenny and Sal Romano, thanks DD."</p> <p>7 A. Right. That's my wife.</p> <p>8 Q. Okay. That's the same Sal Romano</p> <p>9 we've been talking about?</p> <p>10 A. Yes.</p> <p>11 Q. The proofreader?</p> <p>12 A. The proofreader.</p> <p>13 Q. I don't see anything -- the latest</p> <p>14 invoice I see is August 24, 2010. I don't see</p> <p>15 anything more current than that. Can you help me?</p> <p>16 A. No, that should be it.</p> <p>17 Q. August 24, 2010?</p> <p>18 A. Yeah, I didn't do any work.</p> <p>19 Q. So -- so you haven't billed for any</p> <p>20 work since August 24, 2010; is that right?</p> <p>21 A. That is correct. If those are the</p> <p>22 records there. That is a complete set of records.</p> <p>23 Q. I notice that one of the invoices</p> <p>24 you've produced here, invoice statement number 1032,</p> <p>25 which was invoiced on June 21, 2010, describes the</p>
<p style="text-align: right;">Page 451</p> <p>1 your -- from SpyGlass?</p> <p>2 A. No. That's information I received</p> <p>3 from -- probably I received from Motley. I had</p> <p>4 asked for some copies --</p> <p>5 Q. Who made this notebook?</p> <p>6 A. That was made, I believe -- let me</p> <p>7 double check and make sure.</p> <p>8 Q. Is this -- is this a Spyglass notebook</p> <p>9 with your --</p> <p>10 A. Let me just see it. I'll tell you by</p> <p>11 the labeling and whatnot. This is a SpyGlass</p> <p>12 notebook. My wife did this.</p> <p>13 Q. Okay. All right. And the label on</p> <p>14 the front?</p> <p>15 A. Yeah.</p> <p>16 Q. And the handwriting on the front is</p> <p>17 yours, right?</p> <p>18 A. That handwriting is mine.</p> <p>19 Q. It says "MK," Mark Kenny, right?</p> <p>20 A. Yes.</p> <p>21 Q. Legal requirements?</p> <p>22 A. Yeah. That meant that this section of</p> <p>23 the -- of the request for the documents I think is</p> <p>24 Number 5. I tried to put anything that was legally</p> <p>25 or financially related in there.</p>	<p style="text-align: right;">Page 453</p> <p>1 services as consulting experts exhibit review and</p> <p>2 deposition writing, Sal Romano time sheet,</p> <p>3 5/11-6/15?</p> <p>4 A. Uh-huh.</p> <p>5 Q. So Mr. Romano was working with you on</p> <p>6 the report up until you submitted it on June 15?</p> <p>7 A. Yes. Well, he was up to some point.</p> <p>8 I don't know, a week or so before, perhaps.</p> <p>9 Q. And this is for 26 hours of</p> <p>10 Mr. Romano's time?</p> <p>11 A. Right.</p> <p>12 Q. To proofread?</p> <p>13 A. To proofread, and he probably tried to</p> <p>14 do some research. I don't know.</p> <p>15 Q. Twenty-six hours at \$430 an hour,</p> <p>16 total, \$11,180?</p> <p>17 A. Yes.</p> <p>18 Q. And here's an invoice dated May 11,</p> <p>19 2010 showing Sal Romano time sheets 2/26 to</p> <p>20 4/2/2010, 14 and a quarter hours, and time sheets</p> <p>21 from 4/7 to 5/10, 32 hours. For a total of 18 --</p> <p>22 \$19,460 for his time?</p> <p>23 A. Okay.</p> <p>24 Q. Well, you tell me, if I just add those</p> <p>25 two together, 19,000 and 11,000, there's 30,000 for</p>

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<p style="text-align: right;">Page 454</p> <p>1 Sal Romano, not 20,000?</p> <p>2 A. It could be anything, I don't -- I</p> <p>3 have nothing to do with billing. I have nothing to</p> <p>4 do with those numbers. Sal puts them in and gives</p> <p>5 then to Denise.</p> <p>6 Q. And that's -- that's all before the</p> <p>7 \$19,460 between February 26 and May 10. Is that</p> <p>8 before the first draft of the report?</p> <p>9 A. Well, no. I started drafting the</p> <p>10 tables. The tables, remember, I explained that</p> <p>11 I did -- the tables were the beginning of the</p> <p>12 report.</p> <p>13 Q. I was just confused because the first</p> <p>14 report I see is dated January 1, 2010, and you tell</p> <p>15 me it says January 1, 2010, but it doesn't mean</p> <p>16 January 1, 2010?</p> <p>17 A. That is correct.</p> <p>18 Q. And I'm still searching for the date</p> <p>19 of the first draft?</p> <p>20 A. I don't know what the date is.</p> <p>21 Q. Did you tell the plaintiff's lawyers</p> <p>22 that Mr. Romano was billing all of this money just</p> <p>23 to proofread your report?</p> <p>24 A. I didn't tell them anything.</p> <p>25 Q. Did they have any expectation as to</p>	<p style="text-align: right;">Page 456</p> <p>1 A. Yes.</p> <p>2 Q. So you have somewhere between 30 and</p> <p>3 40 more hours to bill?</p> <p>4 A. You mean including deposition, et</p> <p>5 cetera?</p> <p>6 Q. Yes.</p> <p>7 A. If the numbers come out to that.</p> <p>8 Q. So somewhere between 12 and 16,000</p> <p>9 more.</p> <p>10 A. Okay.</p> <p>11 Q. So that will push you over 100,000?</p> <p>12 A. Are we talking about -- for Motley,</p> <p>13 that's correct.</p> <p>14 Q. For Motley as opposed to?</p> <p>15 A. As opposed to my other income.</p> <p>16 Q. Oh, yeah. Okay. But that will push</p> <p>17 you over \$100,000 for your work as an expert witness</p> <p>18 in this case?</p> <p>19 A. That's correct.</p> <p>20 Q. And your work as an expert in this</p> <p>21 case, did you do anything other than review</p> <p>22 documents?</p> <p>23 A. Can you give me an example? No, no.</p> <p>24 Q. Did you do anything other than review</p> <p>25 documents?</p>
<p style="text-align: right;">Page 455</p> <p>1 what Mr. Romano's role --</p> <p>2 A. The original expectation was that it</p> <p>3 would be a co-authored report.</p> <p>4 Q. And -- and would testify by way of</p> <p>5 deposition as an expert witness?</p> <p>6 A. That was the initial expectation.</p> <p>7 Q. So you've brought all of the bills</p> <p>8 that you've sent?</p> <p>9 A. Right.</p> <p>10 Q. And you said that the only time</p> <p>11 remaining is the time that you described earlier</p> <p>12 which was two days before your original 2011</p> <p>13 deposition was set?</p> <p>14 A. Right.</p> <p>15 Q. Where you spent one and a half days,</p> <p>16 14 hours approximately, putting together all of</p> <p>17 these documents?</p> <p>18 A. Correct.</p> <p>19 Q. You want to make sure we don't lose,</p> <p>20 and I understand that.</p> <p>21 A. Correct.</p> <p>22 Q. And then an additional two hours and</p> <p>23 then eight hours to review and reread all of the</p> <p>24 referenced documents, and then another four hours</p> <p>25 with Meghan yesterday, and then the time today?</p>	<p style="text-align: right;">Page 457</p> <p>1 A. No, not that I'm aware of, not that I</p> <p>2 can think of.</p> <p>3 Q. All you did as an expert witness was</p> <p>4 review documents?</p> <p>5 A. Yes.</p> <p>6 Q. Documents that were sent to you by the</p> <p>7 Plaintiff's lawyers?</p> <p>8 A. Documents that were either sent to me</p> <p>9 or were available on the Internet from Crivella</p> <p>10 West.</p> <p>11 Q. You did no original work yourself?</p> <p>12 A. What does that mean?</p> <p>13 Q. I don't know. Did you do any</p> <p>14 independent work.</p> <p>15 A. No.</p> <p>16 Q. In all of the documents that you</p> <p>17 reviewed, you never saw any conclusion by the FDA</p> <p>18 that Mylan was not in full compliance with FDA</p> <p>19 regulations at all times as a wholesale distributor</p> <p>20 of DIGITEK, did you?</p> <p>21 A. I'm sorry. Let me reread that. What</p> <p>22 number is that? Oh, this is a separate question?</p> <p>23 I'm sorry. I thought you were reading from here.</p> <p>24 MR. KAPLAN: Let me ask the court</p> <p>25 reporter to repeat the question.</p>

40 (Pages 454 to 457)

<p style="text-align: right;">Page 458</p> <p>1 (Record read.)</p> <p>2 A. That is correct. I did not see</p> <p>3 Mylan's name.</p> <p>4 Q. Category seven was the witness' entire</p> <p>5 file including all electronic documents and</p> <p>6 correspondence in connection with this matter. And</p> <p>7 I think that's among the documents that you've</p> <p>8 produced including the disks, right?</p> <p>9 A. Correct.</p> <p>10 Q. Number eight calls for documents that</p> <p>11 you received or additional materials since June 29,</p> <p>12 data or writings that you've reviewed or relied</p> <p>13 upon, et cetera, in preparing reports in this</p> <p>14 matter. And I think we've got all of that, don't</p> <p>15 we?</p> <p>16 A. Correct.</p> <p>17 Q. Everything -- number nine is</p> <p>18 everything the witness reviewed that indicates that</p> <p>19 Plaintiffs suggested effective DIGITEK.</p> <p>20 A. I saw nothing.</p> <p>21 Q. So you have no opinions on that?</p> <p>22 A. Absolutely none. I have no interest</p> <p>23 in it.</p> <p>24 Q. Okay. And ten is all notes that the</p> <p>25 witness has taken in connection with review of this</p>	<p style="text-align: right;">Page 460</p> <p>1 Q. At the last deposition, the only</p> <p>2 reports you had were the draft report in front of</p> <p>3 you that shows a date of January 1, 2010 and the</p> <p>4 final report of June 15?</p> <p>5 A. Right. And then I went back into</p> <p>6 electronic records.</p> <p>7 Q. And -- and today, you've brought some</p> <p>8 additional drafts, right?</p> <p>9 A. Correct.</p> <p>10 Q. And we'll go over those. Okay.</p> <p>11 Number 12, all medical, scientific, or other</p> <p>12 literature upon which the witness relies in</p> <p>13 connection with the opinions expressed in the</p> <p>14 reports. Is there any medical, scientific, or other</p> <p>15 literature upon which you are relying?</p> <p>16 A. No, not for this report.</p> <p>17 Q. That covers those documents. Okay.</p> <p>18 Now, let's turn to some other matters.</p> <p>19 I think you told me, I think this was</p> <p>20 kind of off the record, but that your process for</p> <p>21 arriving at your opinions were to construct a time</p> <p>22 line; is that right?</p> <p>23 A. That's correct.</p> <p>24 Q. And then prepare tables?</p> <p>25 A. Yeah, the tables that are attached to</p>
<p style="text-align: right;">Page 459</p> <p>1 matter?</p> <p>2 A. I don't take notes.</p> <p>3 Q. Other than on the documents?</p> <p>4 A. I make the a lot of notes on there.</p> <p>5 Q. Occasionally?</p> <p>6 A. More than occasionally. You saw my</p> <p>7 number of.</p> <p>8 Q. But you don't have a separate set of</p> <p>9 notes chronicling your review of documents?</p> <p>10 A. No, absolutely not.</p> <p>11 Q. All documents that the witness has</p> <p>12 prepared concerning the subject matter of this</p> <p>13 litigation, that's number 11. Are there any</p> <p>14 documents that you've prepared other than reports or</p> <p>15 correspondence?</p> <p>16 A. Nothing.</p> <p>17 Q. And you've brought all reports, draft</p> <p>18 reports, that you've prepared?</p> <p>19 A. Correct.</p> <p>20 Q. At the last deposition, you had your</p> <p>21 final report of June 15, and one draft report, the</p> <p>22 one that's in front of you, which appeared to me</p> <p>23 because I see it on there, to be dated January 1,</p> <p>24 2010, right?</p> <p>25 A. My apologies.</p>	<p style="text-align: right;">Page 461</p> <p>1 the referenced documents.</p> <p>2 Q. When -- when you say "tables attached</p> <p>3 to the referenced documents," can you be more</p> <p>4 precise in explaining what that is?</p> <p>5 A. Well, the table is the referenced --</p> <p>6 the attachments.</p> <p>7 Q. Oh, the attachments to your report?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. So you started by creating the</p> <p>10 time line, and we earlier looked at a time line?</p> <p>11 A. Correct.</p> <p>12 Q. To give you a sense of the chronology,</p> <p>13 right?</p> <p>14 A. Of space, yes.</p> <p>15 Q. And then -- and then that helps you</p> <p>16 then prepare these tables that are attached as</p> <p>17 appendices to your report; is that right?</p> <p>18 A. That is correct.</p> <p>19 Q. So from that information, then, you</p> <p>20 constructed a rough draft of a report?</p> <p>21 A. Correct.</p> <p>22 Q. And then you went from there to revise</p> <p>23 it?</p> <p>24 A. Correct.</p> <p>25 Q. Okay. Your role as an expert witness</p>

41 (Pages 458 to 461)

<p style="text-align: right;">Page 462</p> <p>1 in this case was to determine whether or not Actavis 2 was in compliance with GMPs over the period 2004 to 3 2009, and to determine whether or not Actavis 4 released products that were violative of GMPs; is 5 that right? 6 A. That is correct. 7 Q. Okay. Take a look at the draft report 8 which is in front of you. Do you have that? 9 A. Yes. 10 Q. Who drafted that report and when? 11 A. I drafted it. I don't know the date 12 of it. 13 Q. What is the date that appears on the 14 document? 15 A. It says January 1st, but it is not 16 January 1st. That's a place keeper. 17 Q. It says January 1st, 2010, right? 18 A. Yes. 19 Q. I just honestly don't understand what 20 you mean when you say it wasn't January 1st, 2010, 21 it was just a place keeper. What does that mean? 22 A. It's just when I started formatting 23 the document, I said, well, it's got to have a date, 24 and it will be ultimately the date of the report. 25 So I just kept it as January 1st until I knew when I</p>	<p style="text-align: right;">Page 464</p> <p>1 notes. 2 Q. So this was something more than just 3 proofreading from Sal? 4 A. It was -- you mean -- describe what 5 you mean by proofreading. 6 Q. Well, you -- you told me before that 7 Sal's role was strictly to proofread and correct 8 spelling errors? 9 A. He looked at content and logic. 10 Q. So he had input then into the 11 substance of the report? 12 A. To a degree. 13 Q. And so did the Plaintiff's lawyers? 14 A. No. 15 Q. Did you share this draft with the 16 Plaintiff's lawyers? 17 A. No. 18 Q. All right. Look at the first page. 19 In other words, at this point in time, you did your 20 first draft and you kept it from the Plaintiff's 21 lawyers? 22 A. Correct. 23 Q. Why? 24 A. Because I didn't want to show it to 25 them. I didn't want to get any direction. This is</p>
<p style="text-align: right;">Page 463</p> <p>1 was going to issue the report. 2 Q. Did you do this before or after 3 January 1st, 2010? 4 A. I have to look at my time line. 5 Q. You're now looking -- you've asked for 6 and you're looking at Exhibit, for the record, 135? 7 MS. CARTER: 135. 8 BY MR. KAPLAN: 9 Q. Which are your invoices; is that 10 right? 11 A. Yes. It looks like on or about -- I 12 started making some chronology around March. 13 Q. March of 2010? 14 A. Yes. 15 Q. And this is the first version of the 16 report; is that right? 17 A. That's correct. 18 Q. You have handwritten notes on this 19 report? 20 A. Yes. 21 Q. Does that reflect input that you 22 received from others? 23 A. It reflects a discussion I had with 24 Sal. He was across from me, we went through the 25 report. He read and we discussed, and then I made</p>	<p style="text-align: right;">Page 465</p> <p>1 my report, not theirs. 2 Q. On the first page on the top 3 right-hand corner, it says "second discussion." 4 What does that mean? 5 A. That means Sal and I had talked about 6 this earlier. 7 Q. You also have a note on the first page 8 that says, "my experience," two exclamation points? 9 A. It just means -- I don't know what 10 that means, to be honest with you. 11 Q. Then you have a note that says simply? 12 A. "Sampling" -- wait a minute. 13 Q. "Sampling retained"? 14 A. "Sampling retained." 15 Q. What does that mean? 16 A. I don't know, I honestly don't. 17 Sampling retained? Could be two different notes. 18 Sampling could refer to the 100 percent inspection 19 sampling. Retained, did they look at retained 20 product. That's the only thing I can think of in 21 looking at that note. 22 Q. So, by time you compiled this draft 23 report, you had -- you had reviewed all of the 24 documents that had been sent to you? 25 A. You say sent to me. There was a</p>

42 (Pages 462 to 465)

<p style="text-align: right;">Page 466</p> <p>1 significant amount of information in Crivella West. 2 I tried to take all of the information that I had 3 time to review, and then I also reviewed the CD that 4 you have a copy of which is a duplicate of what's -- 5 Q. Was there any documents -- were there 6 any documents or information that you didn't have at 7 the time that you prepared this first draft report, 8 which we should mark here as Exhibit 140. So we're 9 going to refer to this as 140. My question is: Was 10 there any -- were there any documents or information 11 that you didn't have that you needed to have in 12 order to fully express your opinions? 13 A. I don't recall. I would suspect that 14 since I was in the process of continually reading 15 documents that I saw other documents which could 16 have influenced the revision of this. So this was 17 not a complete -- perhaps complete at this point, I 18 don't recall. 19 (Whereupon, Exhibit 140, first draft 20 report, was marked for identification as of 21 today's date.) 22 Q. So you saw none one way or the other? 23 A. I don't know. 24 Q. Okay. Underneath "my experience," 25 would you interpret your notes there for me, read</p>	<p style="text-align: right;">Page 468</p> <p>1 author? 2 A. Correct. 3 Q. Okay. Then under that, there is a 4 question mark, and then it says once product sent 5 out? 6 A. I don't know what that meant, but it 7 meant something to me at the time. 8 Q. Look on Page 2. It says intro -- I 9 assume that Sal said you should have an 10 introduction? 11 A. Well, we discussed it. It wasn't that 12 Sal -- we discussed it. 13 Q. And concluded that there should be an 14 introduction? 15 A. Yes. 16 Q. And that the summary of the opinions 17 should be moved to the end? 18 A. Yes, it was kind of out of, you know 19 order. 20 Q. And then there is a note that says, 21 "make clear"? 22 A. Where is that? Oh, make clear -- I 23 don't know. Make something, format clear, summary 24 clear, I don't recall. 25 Q. But it was important to have a</p>
<p style="text-align: right;">Page 467</p> <p>1 them. 2 A. That I should focus only on my own 3 experience, and I got to constantly go over this 4 based on my experience. 5 Q. Under that note, "my experience." 6 Only -- 7 A. Oh, only reason recall because -- 8 Q. Admit? 9 A. Admit by -- I don't know. I don't 10 know what it says anymore. 11 Q. Admit by end -- 12 A. I don't know. I can't read my 13 handwriting. 14 Q. You can't read your handwriting? 15 A. No. I'm a lefty. You see what my 16 handwriting looks like. 17 Q. I understand. We all seem to be able 18 to interpret our own though. 19 A. Not in that case. I can't. 20 Q. You can't do it? 21 A. No, I can't. 22 Q. What would make sense to you there? 23 A. I can't -- I can't help you on that 24 one. 25 Q. Okay. So illegible even to the</p>	<p style="text-align: right;">Page 469</p> <p>1 one-page summary of your opinions, right? 2 A. It sounded like a good idea at the 3 time, yeah. 4 Q. Well, that's what you ended up with, 5 wasn't it, a one-page summary of your opinions? 6 A. I believe so, yeah. 7 Q. On Page 3, there's a note that says 8 "one first recalled, arrow double thick." 9 A. Right. 10 Q. What does that mean? 11 A. Just saying that the first recall was 12 only for double thick. 13 Q. And then two, you have written 14 "active." What does that mean? 15 A. I don't know. 16 Q. Read -- read your other notes here on 17 page three of your first draft report marked Exhibit 18 140. 19 A. Systems illustrate more of a systems 20 problem, treatment of evidence, looks like 21 treatment, not exhaustive list, just examples. 22 Forty-three reflects -- reflect fact findings. 23 There are four different investigations associated 24 with something but not by name. 25 Q. By the way, that first recall that you</p>

43 (Pages 466 to 469)

<p style="text-align: right;">Page 470</p> <p>1 noted about double thick, that was as to DIGITEK 2 only, wasn't it? 3 A. Yes. 4 Q. You have a note on the left-hand side 5 that says everybody will get asked about? 6 A. Every -- it's everything. 7 Q. Will get? 8 A. Will get asked about. 9 Q. What does that mean? 10 A. Meaning that you have to understand 11 what you're writing, make sure that you can 12 substantiate what you're writing. 13 Q. Did somebody have to tell you that? 14 A. Reinforce it perhaps, I don't know. 15 Q. Did Sal tell you that? 16 A. No, he did not tell me that. 17 Q. Did you tell yourself that? 18 A. I told myself that. 19 Q. Okay. Then on page 4, you have a 20 note, "qualify background," is that what that is? 21 A. Yeah. In other words, introduce 22 earlier what your background is and do a summary of 23 it. We had looked at some of the -- anyway, that's 24 what that means. 25 Q. Is that Sal's advice?</p>	<p style="text-align: right;">Page 472</p> <p>1 Romano, right? 2 A. Yes, or myself, or in reviewing it 3 myself. 4 Q. The draft report, if you look on page 5 28, has references listed, right? 6 A. Yes, the beginning of references. 7 Q. Now, nowhere in this draft report is 8 there any opinion with regard to Mylan, is there? 9 A. In this report? 10 Q. Well, let's look on Page 2, the 11 summary of your opinion. Is there anything in there 12 with regard to Mylan? 13 A. I don't see anything at this 14 particular revision level, no. 15 Q. So in Exhibit 40, there is no opinion 16 that you expressed as to Mylan? 17 A. At that particular point, that's 18 correct. I had not looked at the Mylan documents. 19 I only looked at the plaintiff documents and 20 whatever else is listed. There were probably more. 21 Q. On page 20 of your draft report, 22 Exhibit 140 that you're looking at, there is a 23 SpyGlass Group summary. Do you see that? 24 A. Yes. 25 Q. You wrote that?</p>
<p style="text-align: right;">Page 471</p> <p>1 A. No, I don't think so. 2 Q. On page five, you have a note that 3 says, "In the body of this report, only the company 4 name Actavis will be used." And then next to it, 5 "Done." 6 A. Yeah. What that means is I got up 7 front -- I -- I wanted to make sure that it was 8 clear that I was going to use the term Actavis and 9 not waffle back and forth depending upon the time 10 period, calling it Amide and then calling it Actavis 11 at a later time. So I wanted to make sure that I 12 defined in the introduction that when I referred to 13 Actavis, I referred to this organization which 14 originally was known as Amide. 15 Q. And then at the bottom on page five, 16 you have a handwritten note that says, "more detail 17 intro"? 18 A. Yeah. 19 Q. What's does that mean? 20 A. I assumed that we discussed it and 21 that the introduction didn't -- there was not enough 22 in the introduction and that -- helping organize it. 23 Q. The various other notes are made by 24 you. I'm going to try to get through this as 25 quickly as a result of your discussion with Sal</p>	<p style="text-align: right;">Page 473</p> <p>1 A. Yes. 2 Q. You started off with, "Actavis 3 demonstrated a general incompetence in the handling 4 of this critical product quality." Right? 5 A. Yes. 6 Q. Then you go on, and you end with the 7 "Actavis environment was not focused on GMP and 8 quality systems." 9 A. Right. 10 Q. Not one word as to Mylan? 11 A. That's correct. 12 MR. KAPLAN: Let's let him change the 13 tape. 14 THE VIDEOGRAPHER: We're off the 15 record. The time is 3:11. This is the end 16 of tape 3. 17 (Recess taken.) 18 THE VIDEOGRAPHER: We are back on the 19 record. The time is 3:16. This is the 20 beginning of tape 4. 21 BY MR. KAPLAN: 22 Q. We're looking at your initial draft 23 report marked Exhibit 140 which shows on page 1 a 24 date of January 1, 2010? 25 A. Yes.</p>

44 (Pages 470 to 473)

<p style="text-align: right;">Page 474</p> <p>1 Q. We've gone through the report and 2 looked at notes that you have made, and you said 3 those were based on discussions you had with Sal 4 Romano? 5 A. Either by myself or with discussions 6 with Sal, yes. 7 Q. At least two discussions with Sal? 8 A. Two discussions with Sal, right. 9 Q. In fact, the notes from also based 10 upon discussions that you had with Meghan Carter and 11 Pete Miller as well? 12 A. I don't know. Could you explain where 13 they're at, I mean specifically? 14 Q. I'm asking you; is that right? 15 A. No, no, not at all. 16 Q. You are sure about that? 17 A. I'm positive about that. 18 Q. You sent a draft to Meghan and Pete, 19 didn't you? 20 A. No. I did not send a draft to Meghan 21 and Pete. 22 Q. Are you absolutely certain of that? 23 A. I'm certain of it, yes. 24 Q. And when you testified under oath on 25 June 29, 2010 and gave a deposition in this case and</p>	<p style="text-align: right;">Page 476</p> <p>1 story? 2 A. Well, I guess I'm confused. The -- I 3 did have a meeting, I did send it. I didn't think 4 it was this particular revision, because it doesn't 5 look like any of the notes that -- I guess it is. I 6 don't know. I -- 7 Q. You just swore under oath that you did 8 not send the initial draft to Pete and Meghan. 9 That's not true, is it? 10 A. I'd have to go back through my 11 e-mails. 12 MS. CARTER: Objection. 13 A. I -- I don't recall -- as of right 14 now, I don't recall sending this revision to Meghan 15 and Pete. I do not recall doing that. 16 BY MR. KAPLAN: 17 Q. Your sworn testimony when you were 18 deposed on June 29, 2010 was that you did send this 19 draft report to Meghan and Pete, wasn't it? 20 A. Yes. 21 Q. Are you telling the truth now or were 22 you telling the truth then? 23 A. To the best of my recollection right 24 now, I did not send it. I'd have to recreate 25 through e-mails, et cetera. I did send them a copy</p>
<p style="text-align: right;">Page 475</p> <p>1 gave sworn testimony, on Page 215, you were asked by 2 Mr. Moriarty: "To whom did you send this draft," 3 your answer: "I sent it to Meghan, Sal, and Pete." 4 Question: "Was this a first draft?" 5 Answer: That was a first draft, the 6 draft that they saw, right." 7 Question: "And then in here, there is 8 handwriting. Is it your handwriting?" 9 Answer: "All of it is mine." 10 Question: "Is the handwriting based on 11 discussions you had with Plaintiff's counsel about 12 the draft." 13 Answer: "It is based upon two things or 14 three, if you will, one, listening to them; 15 secondly, coming up with ideas as I'm just going 16 through the document, and then later going back and 17 looking at it and making additional edits as I 18 reread it." 19 That was your sworn testimony on June 29, 20 2010, wasn't it? 21 A. If you said that then, that is my 22 sworn testimony, yes. 23 Q. You said it? 24 A. Yeah, I understand that. 25 Q. And today, you're telling a different</p>	<p style="text-align: right;">Page 477</p> <p>1 at one point. I thought I recollected that was in 2 June. 3 Q. Let me show you that testimony that I 4 just quoted and see if there's any doubt in your 5 mind that you said on June 29, 2010 that you sent 6 this draft to Meghan and Pete. 7 A. June 29th? 8 Q. That's when you were deposed. 9 A. No, I understand that. 10 Q. I'm going to put in front of you your 11 sworn deposition testimony on June 29, 2010, and I 12 will refer you to Page 215 beginning at line 21 and 13 continuing through Page 216 line 17. Do you see it? 14 A. Just kind of point to it, if you 15 would. 16 Q. (Indicating.) I'm going to mark -- 17 I'm going to mark these lines for you, and ask you 18 to read that testimony. You read that testimony. 19 A. Okay. Last document I'm holding 20 appears to be a draft for discussion purposes only. 21 Q. Start again, please, and read slower. 22 A. Question: "Okay. The last document 23 I'm holding here appears to be a draft for 24 discussion purposes only version of your report; is 25 that correct?"</p>

45 (Pages 474 to 477)

<p style="text-align: right;">Page 478</p> <p>1 Correct. 2 To whom did you send this draft? 3 I sent it to Meghan, Sal, and Pete. Was 4 it the first draft? That was a first draft. 5 The first draft that they saw, right. 6 Right." 7 Q. That's not a question; that's your 8 statement, isn't it? 9 A. Yeah, I'm reaffirming it. 10 Q. The first draft that they saw, right. 11 A. "And then in here, there is 12 handwriting. Is it your handwriting. 13 All of it is mine. 14 Is the handwriting based on discussions 15 you had with Plaintiff's counsel about the draft? 16 It's based upon two things or three, if 17 you will, one, listening to them. Secondly, coming 18 up with ideas as I'm going through the document, and 19 then later going back and looking at and making 20 additional edits as I reread." 21 So, it looks like that my memory is 22 failing me right now that I did send this document 23 to them and discuss it. 24 Q. So when you denied sending the first 25 draft of the document to Meghan and Pete, that was</p>	<p style="text-align: right;">Page 480</p> <p>1 have not gone through the Mylan documents. 2 Q. Who asked you that question? 3 A. I believe it was Pete Miller. He had 4 a question. And I said I have not gone through it. 5 And he says, well, do you have any opinion. I said 6 I have to read the Mylan document. I didn't even 7 open them up. 8 Q. At this point in time when you got to 9 the point of drafting an opinion that is 35 pages 10 long that you shared with your colleague, Sal 11 Romano, that you shared with Plaintiff's lawyers, 12 Pete Miller and Meghan Carter, you hadn't looked at 13 any Mylan documents? 14 A. I had not looked at any Mylan 15 documents at that point. 16 Q. Did you have any idea that Mylan was a 17 defendant in this lawsuit? 18 A. No, I actually did not. I didn't know 19 what their role was in terms of the legal situation. 20 I was asked to look at two -- initially asked to 21 look at different things which is in this report. 22 And they had questions, did I look at Mylan, and I 23 said no, I haven't looked at any information 24 regarding Mylan. And they directed me, it's under 25 Crivella West under so and so tab, et cetera, and I</p>
<p style="text-align: right;">Page 479</p> <p>1 not the truth? 2 A. That was not accurate. 3 Q. And when you said that the Plaintiff's 4 lawyers, Pete Miller and Meghan Carter, had no input 5 into your report, that was inaccurate? 6 A. No. They had no substantive input 7 into the report. In other words, the data, the 8 conclusions. They couldn't because this is my 9 report, my thinking. I wouldn't allow anybody to 10 persuade me into saying something that was not true. 11 Q. In your report, this report that we're 12 referring to, Exhibit 140, says not one word about 13 Mylan? 14 A. That's correct. 15 Q. In fact, that report, Exhibit 140, 16 says, "In body of this report, only the company name 17 Actavis will be used." Correct? 18 A. That is referring to -- yes, that's 19 correct, it does say that. 20 Q. Somebody told you, gee, Mr. Kenny, 21 we've looked at your report here, your initial 22 draft, Exhibit 140, and you don't say anything about 23 Mylan. You better add something about Mylan. 24 A. I was asked a question, have you -- 25 have you gone through the Mylan documents? I said I</p>	<p style="text-align: right;">Page 481</p> <p>1 went to -- I went to the tab, I started reading it. 2 And I made some conclusions off of the information 3 that I read, but that's the extent of the direction. 4 Q. In your 35 page draft report, Exhibit 5 140, you mention not one word about Mylan, and 6 others reviewed it and said you better express 7 opinions about Mylan because that's what we want? 8 MS. CARTER: Objection. 9 A. No, that's not even remotely close, 10 the way you put it. They asked me very specifically 11 have you had an opportunity to look at Mylan, and I 12 said no. They said the Mylan documents are in 13 Crivella West under dot, dot, dot, and -- anyway, so 14 then I took a look at them. 15 BY MR. KAPLAN: 16 Q. So now you remember a specific 17 conversation with the Plaintiff's lawyers in which 18 they asked you have you looked at the Mylan 19 documents? 20 A. I thought it was a later discussion. 21 Quite honestly, I thought it was later in perhaps 22 the discussion process. 23 Q. Until I confronted you with your sworn 24 testimony on pages 215 and 216 of your previous 25 deposition of June 29, 2010, you denied sending this</p>

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<p style="text-align: right;">Page 482</p> <p>1 report to the plaintiff's lawyers?</p> <p>2 MS. CARTER: Objection.</p> <p>3 BY MR. KAPLAN:</p> <p>4 Q. Correct?</p> <p>5 A. It appears that is correct.</p> <p>6 Q. Appears?</p> <p>7 A. Yeah.</p> <p>8 Q. It is incorrect? It is correct?</p> <p>9 A. No, you're right. It is incorrect. I</p> <p>10 misspoke. I didn't lie, I misspoke. You know, in</p> <p>11 trying to put together the sequence, the chronology,</p> <p>12 I misspoke.</p> <p>13 Q. Let's look at the next draft of your</p> <p>14 report.</p> <p>15 (Whereupon, Exhibit 141, Draft of</p> <p>16 expert opinion report, was marked for</p> <p>17 identification as of today's date.)</p> <p>18 BY MR. KAPLAN:</p> <p>19 Q. I've put before you Exhibit 141 which</p> <p>20 is a subsequent draft of your expert opinion report.</p> <p>21 And I will say for the record, according to the disk</p> <p>22 that you gave me this morning, it is identified as</p> <p>23 expert opinion report May 26, 2010.</p> <p>24 A. Right.</p> <p>25 Q. Is that correct?</p>	<p style="text-align: right;">Page 484</p> <p>1 Q. Exhibit 141, which I've just handed</p> <p>2 you, is a subsequent draft of your expert report,</p> <p>3 correct?</p> <p>4 MS. CARTER: Objection.</p> <p>5 A. No. This is a -- this precedes -- 141</p> <p>6 precedes 140.</p> <p>7 BY MR. KAPLAN:</p> <p>8 Q. Okay. So 140 was a more advanced form</p> <p>9 of your report?</p> <p>10 A. Yes, that's correct.</p> <p>11 Q. Okay. And even though you had an</p> <p>12 initial -- prepared an initial draft which is 141.</p> <p>13 A. Right.</p> <p>14 Q. Then you got to 140 when you had time</p> <p>15 to further review documents, right?</p> <p>16 A. Or further review and -- and collect</p> <p>17 my thoughts.</p> <p>18 Q. And think about it, collect your</p> <p>19 thoughts, be comprehensive?</p> <p>20 A. Yes.</p> <p>21 Q. And -- and Exhibit 140, the draft</p> <p>22 report that came after the initial draft report, you</p> <p>23 said nothing about Mylan, right?</p> <p>24 A. That is correct.</p> <p>25 Q. Okay. Well, let's look at 141 which</p>
<p style="text-align: right;">Page 483</p> <p>1 A. Yes.</p> <p>2 Q. Is that your next --</p> <p>3 A. My next what? Sorry, sir?</p> <p>4 Q. Pardon? Is that your next report?</p> <p>5 A. No. This is the prior report. This</p> <p>6 looks to me like the prior report.</p> <p>7 Q. Prior to?</p> <p>8 A. Prior to this report (indicating).</p> <p>9 Q. So are you telling me that Exhibit 141</p> <p>10 was your first report?</p> <p>11 A. Yes, there's no question.</p> <p>12 Q. No question. How do you know that?</p> <p>13 A. Take a look at -- I had a lot of place</p> <p>14 keepers. I mean sections that I need to consider.</p> <p>15 Q. I'm sorry, tell me how it is that you</p> <p>16 concluded that Exhibit 141 was drafted before?</p> <p>17 A. Well, in quickly looking at it, you</p> <p>18 know, it looks like this is a more complete document</p> <p>19 and more filled in than this one. This one</p> <p>20 meaning -- okay. The one document that has all of</p> <p>21 the (indicating) --</p> <p>22 Q. Look at the exhibit number and let's</p> <p>23 get -- let's be clear on the record.</p> <p>24 A. So what's -- what's your question,</p> <p>25 sir?</p>	<p style="text-align: right;">Page 485</p> <p>1 you say was your initial draft report; is that</p> <p>2 right?</p> <p>3 A. Yes.</p> <p>4 Q. Summary of the opinions is on page 1.</p> <p>5 And there is nothing, there is no opinion</p> <p>6 whatsoever, is there, as to Mylan?</p> <p>7 A. That is correct.</p> <p>8 Q. On Page 2, you state in the</p> <p>9 introduction that it's not only you but it's Mark</p> <p>10 Kenny and Salvatore Romano who have been engaged by</p> <p>11 Motley Rice to prepare an expert report?</p> <p>12 A. That is correct.</p> <p>13 Q. That you, Mark Kenny, and Salvatore</p> <p>14 Romano had been engaged to participate in a legal</p> <p>15 deposition?</p> <p>16 A. That is correct.</p> <p>17 Q. And that you, Mark Kenny, and</p> <p>18 Salvatore Romano, have been engaged to testify as an</p> <p>19 expert witness at trial?</p> <p>20 A. Yes.</p> <p>21 Q. And then you refer to the expert</p> <p>22 opinion as "our expert opinion," right?</p> <p>23 A. That is correct.</p> <p>24 Q. So in the -- in the subsequent draft</p> <p>25 which is marked as Exhibit 141 -- I'm sorry.</p>

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<p style="text-align: right;">Page 486</p> <p>1 In the initial draft, you make it clear</p> <p>2 that this is going to be a joint report from you and</p> <p>3 Sal, that you're both going to be experts to testify</p> <p>4 at deposition and trial?</p> <p>5 A. Correct.</p> <p>6 Q. And then you pull that idea down in</p> <p>7 the -- in the second draft which is 141?</p> <p>8 A. Correct.</p> <p>9 Q. Okay. To -- to be correct, and make</p> <p>10 sure that -- if you look at Exhibit 140, which you</p> <p>11 said was the subsequent draft?</p> <p>12 A. Right.</p> <p>13 Q. You say in there too on page 5 that</p> <p>14 it's you and Sal Romano?</p> <p>15 A. Right, and his name appears on the</p> <p>16 front.</p> <p>17 Q. Yeah. So let's look at what you say</p> <p>18 is your initial report, Exhibit 141, which you</p> <p>19 agreed says nothing about Mylan in the summary of</p> <p>20 your opinion, right?</p> <p>21 A. Correct.</p> <p>22 Q. And that's in -- that's in a black box</p> <p>23 on the first page, right?</p> <p>24 A. Black box?</p> <p>25 Q. First page of 141?</p>	<p style="text-align: right;">Page 488</p> <p>1 of it because I -- because I wanted input only into</p> <p>2 spelling, format, completeness.</p> <p>3 Q. So you threw out what his input as to</p> <p>4 substantive content of your report?</p> <p>5 A. Well, it was not substantive comment.</p> <p>6 It was -- I had no interest in it.</p> <p>7 Q. Okay.</p> <p>8 A. Because I was the one that was going</p> <p>9 to write the report and I was the one that was going</p> <p>10 to testify, not him.</p> <p>11 Q. Exactly. So on page 16 of the initial</p> <p>12 draft report marked Exhibit 141, when Sal Romano</p> <p>13 said to you, "We need to write a dialogue followed</p> <p>14 by bullet points on the following," and if you look</p> <p>15 down to the fifth and sixth bullet points or the</p> <p>16 fifth bullet point, it says, "Mylan was negligent in</p> <p>17 controlling its contractor, Actavis. Lack of</p> <p>18 visits, audits, and follow-up. That was his</p> <p>19 direction to you, right? Incorporate that in a</p> <p>20 bullet point. He told you to do that, didn't he?"</p> <p>21 MS. CARTER: Objection.</p> <p>22 A. I need to read it, sir.</p> <p>23 BY MR. KAPLAN:</p> <p>24 Q. Do you see the fifth bullet point?</p> <p>25 A. Yes, sir.</p>
<p style="text-align: right;">Page 487</p> <p>1 A. Oh, the box.</p> <p>2 Q. Summary of opinion, black box, right?</p> <p>3 Isn't that right?</p> <p>4 A. Yes.</p> <p>5 Q. And if you look at page 14 where it</p> <p>6 says "SpyGlass Group Conclusion." Do you see that?</p> <p>7 On Exhibit 141?</p> <p>8 A. Yes.</p> <p>9 Q. Nothing there pertaining to Mylan, is</p> <p>10 there?</p> <p>11 A. Nothing.</p> <p>12 Q. Then look at page 16. There's a</p> <p>13 heading, "Overall observations of the quality system</p> <p>14 at Actavis." Underneath that, there is a note,</p> <p>15 "Mark, we need to write a dialogue followed by</p> <p>16 bullet points on the following."</p> <p>17 Who do you think that is from? Would it</p> <p>18 be Sal Romano?</p> <p>19 A. Yes.</p> <p>20 Q. So Sal Romano, who you described</p> <p>21 earlier as somebody who just checked your spelling</p> <p>22 and was a proofreader, was giving you substantive</p> <p>23 input as to the content of your report?</p> <p>24 A. He attempted to. He attempted to give</p> <p>25 me substantive information of which I eliminated all</p>	<p style="text-align: right;">Page 489</p> <p>1 Q. That is Sal telling you to put this</p> <p>2 bullet point in saying Mylan was negligent in</p> <p>3 controlling its contractor, Actavis, lack of visits,</p> <p>4 audit, and follow-ups. That's what it says, isn't</p> <p>5 it?</p> <p>6 A. Yes.</p> <p>7 Q. But when you prepared the subsequent</p> <p>8 report marked Exhibit 140, you rejected that and</p> <p>9 didn't include such a bullet point, did you?</p> <p>10 A. At that point, I did not include it,</p> <p>11 that's correct, because I threw out basically</p> <p>12 anything that he told me.</p> <p>13 Q. Well, if you look at Page 18 of your</p> <p>14 final report dated June 15, 2010, you didn't reject</p> <p>15 his first bullet point, did you? Do you have your</p> <p>16 final report in front of you?</p> <p>17 A. Yes.</p> <p>18 Q. You accepted some things he told you</p> <p>19 and you rejected others. Right?</p> <p>20 MS. CARTER: Objection.</p> <p>21 BY MR. KAPLAN:</p> <p>22 Q. Are you looking on Page 18 of your</p> <p>23 final report?</p> <p>24 A. That is correct. That is correct</p> <p>25 in -- could you ask the question --</p>

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<p style="text-align: right;">Page 490</p> <p>1 Q. Did you say that the corporate culture 2 was production at any cost and ignore the quality 3 systems? 4 A. Did I say that? No, these were -- 5 these were Sal's ideas. 6 Q. And did you incorporate that on Page 7 18 of your final report? 8 A. Some of the information I did 9 incorporate after review of the documents. 10 Q. Specifically, I'm looking at the first 11 bullet point and asking you whether you accepted 12 Sal's direction as to the substantive content of 13 your final report when he suggested that you say, 14 "the corporate culture was production at any cost 15 and ignore the quality systems." You said that as 16 to Actavis, didn't you? 17 MS. CARTER: Objection. 18 A. Yes. 19 BY MR. KAPLAN: 20 Q. So you accepted that? 21 A. I accepted it because I agreed with 22 it. 23 Q. Okay. And then look on the second and 24 third bullet points, page 14 of your final report, 25 includes his suggestions that you say that "Actavis'</p>	<p style="text-align: right;">Page 492</p> <p>1 you should say that many drug products were made and 2 sold without approved NDAs/ANDA showing arrogance or 3 a complete lack of knowledge of regulatory 4 requirements? 5 A. I never did anything with that -- 6 MS. CARTER: Objection. 7 A. Ultimately. 8 BY MR. KAPLAN: 9 Q. Look at your final report, page 14. 10 Your final report is Exhibit 38. Do you have that 11 in front of you? Page 14. Look at the last full 12 paragraph. You parrot Sal Romano's words that say 13 "Additionally, there was a lack of understanding of 14 the regulatory approval process since many drug 15 products were made and sold without approved 16 NDA/ANDAs." Right? 17 MS. CARTER: Objection. 18 A. I don't recall, to be honest with you. 19 BY MR. KAPLAN: 20 Q. Well, just look at -- look at the 21 words. You don't have to recall anything, you just 22 have to look at page 14. 23 A. Fourteen, which bullet? 24 Q. Page 14 of your final report, Exhibit 25 38?</p>
<p style="text-align: right;">Page 491</p> <p>1 corporate and QA management was weak and not 2 knowledgeable of the CGMP." You said that in your 3 final report, didn't you? 4 A. Not in my final report. 5 Q. Okay. Look on page 14, the last 6 paragraph, you make the statement, "It is my opinion 7 to a reasonable degree of certainty that corporate 8 and QA management were not knowledgeable of the 9 CGMP." 10 A. Yeah. I didn't say anything about 11 weak. Those are not terms that I would use. 12 Q. So we're going to parse out the word 13 "weak"? 14 A. No, it's an important word. 15 Q. Okay. But you did follow the 16 suggestion to include the statement that "Actavis' 17 corporate and QA management were not knowledgeable 18 of the CGMP." Except to that, right? 19 MS. CARTER: Objection. 20 A. I accepted that because it agreed 21 with -- 22 BY MR. KAPLAN: 23 Q. Same with -- same with the next bullet 24 point. With regard to Sal's direction as to the 25 substantive content of your report telling you that</p>	<p style="text-align: right;">Page 493</p> <p>1 A. Which bullet? 2 Q. There's no bullet. It's Exhibit 38. 3 A. Oh, here, yeah. So I understand, I 4 want to read what you're saying that I parroted. 5 Q. You parroted these words, "many drug 6 products were made and sold without approved 7 NDAs/ANDAs," I think you eliminated the words 8 "showing arrogance." But then you used "evidencing 9 a complete lack of knowledge or regulatory 10 requirements." 11 MS. CARTER: He's on the wrong page on 12 that one. 13 BY MR. KAPLAN: 14 Q. Are you on page 14 of Exhibit 38, 15 your final report dated June 15, 2010? 16 A. Yes, but I'm on the wrong page when it 17 comes to this, I guess (indicating). 18 Q. Look on page 16 of your initial draft 19 report. 20 MR. ANDERTON: Exhibit 141. 21 BY MR. KAPLAN: 22 Q. Yes. Where Sal Romano is giving you 23 direction on the content of the report? 24 MS. CARTER: Objection. 25 A. Okay. Could you please show me? I'm</p>

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<p style="text-align: right;">Page 494</p> <p>1 looking at page 16.</p> <p>2 MR. ANDERTON: You're on Exhibit 140,</p> <p>3 go to 141, Page 16 of Exhibit 141.</p> <p>4 A. Got it.</p> <p>5 MR. ANDERTON: Look at the third</p> <p>6 bullet point.</p> <p>7 A. And your question is? One more time</p> <p>8 so I understand it.</p> <p>9 BY MR. KAPLAN:</p> <p>10 Q. That's fine. Let's go through it.</p> <p>11 A. Sure.</p> <p>12 Q. If you're looking at page 16 of</p> <p>13 Exhibit 141 where Sal Romano is giving you direction</p> <p>14 as to the suggested content of the expert report to</p> <p>15 be submitted in this case, in the third bullet</p> <p>16 point, he says that you need to say the following:</p> <p>17 "Many drug products were made and sold without</p> <p>18 approved NDA/ANDA showing arrogance or a complete</p> <p>19 lack of knowledge of regulatory requirements."</p> <p>20 He's suggesting that you say that as to</p> <p>21 Actavis, right?</p> <p>22 MS. CARTER: Objection.</p> <p>23 A. He's saying that that's his opinion.</p> <p>24 BY MR. KAPLAN:</p> <p>25 Q. Right. And then in your final report</p>	<p style="text-align: right;">Page 496</p> <p>1 points on the following," and the third bullet</p> <p>2 point, he uses the term "showing arrogance"?</p> <p>3 A. Right.</p> <p>4 Q. And you -- you adopted those words,</p> <p>5 didn't you, in your final report on page 14?</p> <p>6 A. I wrote similar content. I didn't</p> <p>7 write -- I didn't write the same words, I'm sure.</p> <p>8 Q. Quote, page 14 of your report June 15,</p> <p>9 2010, Exhibit 38, "It is my opinion to a reasonable</p> <p>10 degree of certainty that they" -- meaning Actavis --</p> <p>11 were highly resistant to systematic change,</p> <p>12 appearing sure that minor improvements would resolve</p> <p>13 all of their issues. This was a flawed strategy.</p> <p>14 Their arrogance resulted in managing a drug company</p> <p>15 that operated at a high risk level." Correct?</p> <p>16 A. Correct what?</p> <p>17 Q. Isn't that what you said?</p> <p>18 A. That's what I said.</p> <p>19 Q. You followed Sal's direction as to the</p> <p>20 content of your report?</p> <p>21 MS. CARTER: Objection.</p> <p>22 BY MR. KAPLAN:</p> <p>23 Q. Didn't you?</p> <p>24 A. We had -- we had discussions. Sal did</p> <p>25 not direct me, nobody directs me. We had technical,</p>
<p style="text-align: right;">Page 495</p> <p>1 which is Exhibit 38, on page 14, you say as follows:</p> <p>2 "Apparently, there was a lack of understanding of</p> <p>3 the regulatory approval process since many drug</p> <p>4 products were made and sold without approved</p> <p>5 NDA/ANDAs," citing footnote ten. Isn't that what</p> <p>6 you said --</p> <p>7 A. Yes.</p> <p>8 Q. -- in your final report?</p> <p>9 A. That is in my final report.</p> <p>10 Q. So you followed the direction of Sal</p> <p>11 Romano as to the substantive content of your final</p> <p>12 report on that issue, didn't you?</p> <p>13 MS. CARTER: Objection.</p> <p>14 A. I agreed with Sal. I did not follow</p> <p>15 his direction. There's a big difference.</p> <p>16 BY MR. KAPLAN:</p> <p>17 Q. You adopted Sal's characterization</p> <p>18 that Actavis demonstrated or showed arrogance,</p> <p>19 right?</p> <p>20 MS. CARTER: Objection.</p> <p>21 A. Sal?</p> <p>22 BY MR. KAPLAN:</p> <p>23 Q. Look at the fourth bullet point on</p> <p>24 page 16 of Exhibit 141 where Sal Romano is saying to</p> <p>25 you, "We need to write a dialogue followed by bullet</p>	<p style="text-align: right;">Page 497</p> <p>1 if you will, professional discussions. From that, I</p> <p>2 made conclusions. It's that simple. I was being</p> <p>3 respectful at that point.</p> <p>4 Q. So you were being respectful by</p> <p>5 including what Sal told you to say in your final</p> <p>6 report?</p> <p>7 A. I was being respectful and listening</p> <p>8 to him.</p> <p>9 MS. CARTER: Objection.</p> <p>10 BY MR. KAPLAN:</p> <p>11 Q. And adopting --</p> <p>12 A. No. I was not being respectful and</p> <p>13 adopting, I was being -- if I agreed with it, I</p> <p>14 wouldn't put it in. If I didn't agree with it, I</p> <p>15 would not put it in.</p> <p>16 Q. Let's look again at Exhibit 141 on</p> <p>17 Page 16. This is your initial draft report in this</p> <p>18 case. You see the heading review of "Actavis GMP</p> <p>19 compliance history-all products"?</p> <p>20 A. Yes.</p> <p>21 Q. Below that in parenthesis is a note</p> <p>22 from Sal Romano to you?</p> <p>23 A. Right.</p> <p>24 Q. "Mark, dot dot dot, I have added your</p> <p>25 stuff on GMP. Please add some dialogue, dot dot</p>

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<p style="text-align: right;">Page 498</p> <p>1 dot. I do not see -- I did not do a good fit of all 2 of your tables into this dock, exclamation point. 3 Maybe the table details should be as an attachment? 4 I think the following section on DIGITEK is good, 5 dot dot dot. Can you get this section in the same 6 bullet format?" And then the following section is 7 "SpyGlass Group conclusion result of FDA 8 documentation." Do you see that? 9 A. Yes. 10 Q. Would you agree that this is further 11 evidence that Sal Romano gave you direction as to 12 the substantive content of your final expert report 13 and opinions in this case? 14 A. Absolutely not. I would say that he 15 assisted in trying to help me organize it. Going 16 through and reviewing it and trying to make it into 17 a highly organized report and understandable. 18 Q. Sounds like he was more than a spell 19 checker or proofreader, doesn't it? 20 A. Helped me organize. 21 Q. Now -- now he's spell checker, 22 proofreader, and organizer? 23 A. Yeah. I mean, I guess I would say 24 yes. 25 Q. So I don't have any other draft</p>	<p style="text-align: right;">Page 500</p> <p>1 was marked for identification as of today's 2 date.) 3 BY MR. KAPLAN: 4 Q. I'm going to hand you what we've 5 marked as Exhibit 142, which is 21CFR section 203.3, 6 subparagraph B, defines authorized distributor of 7 record. And I want you to take a look at that and 8 then read that into the record as soon as she marks 9 it. 10 A. And that's what number? 11 Q. 203.3b, as in boy, where it says 12 "authorized distributor of record." Do you see 13 that? 14 A. 203. 15 Q. Point 3, subparagraph B. What does it 16 say? 17 A. "Authorized distributor, distributor 18 of record." 19 Q. Read it. 20 A. "Authorized distributor of record 21 means a distributor with whom a manufacturer has 22 established an ongoing relationship to distribute 23 such manufacturers' products." 24 Q. So Mylan was an authorized distributor 25 of record?</p>
<p style="text-align: right;">Page 499</p> <p>1 reports. I have exhibit 141 which were just talking 2 about which you told me is the initial draft report. 3 I have Exhibit 140 which you told me is the next 4 draft report? 5 A. Right. 6 Q. And then I have your final report 7 dated June 15, 2010? 8 A. Right. 9 Q. Are there any others? 10 A. No. 11 Q. Mylan's role was that of an authorized 12 distributor of record and wholesale distributor, 13 correct? 14 A. Correct. 15 Q. Under 21CFR 203.3, an authorized 16 distributor of record means the distributor with 17 whom a manufacturer has established an ongoing 18 relationship to distribute such manufacturer's 19 products, correct? 20 A. Okay. If you say -- I'm not familiar 21 with that phraseology. 22 Q. Would you like me to show you that 23 regulation? 24 A. Surely. 25 (Whereupon, Exhibit 142, Regulation,</p>	<p style="text-align: right;">Page 501</p> <p>1 A. I don't know that term. 2 Q. Well, you see it, I've just showed it 3 to you. 4 A. I see it, but I don't know the context 5 of this, and I am not the right person to give an 6 interpretation of the meaning of that. 7 Q. Isn't it important to you, fundamental 8 to your opinions in this case, to know what Mylan's 9 legal status and responsibility was? 10 A. I don't know if it's important or not, 11 sir. 12 Q. Well, you can't make up something 13 about their -- their legal duties and 14 responsibilities, can you? 15 A. I'm sorry? 16 Q. It's not Kenny on the law, it's what 17 the law is? 18 A. Correct. And the law is good 19 manufacturing practices, of which I understand 20 fully. 21 Q. I move to strike that because that 22 really makes no sense. 23 MS. CARTER: Objection. 24 BY MR. KAPLAN: 25 Q. Look at 21CFC 203.3, Exhibit 142,</p>

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<p style="text-align: right;">Page 502</p> <p>1 subparagraph D, defining wholesale distributor, and 2 tell me if you agree that Mylan is not only -- is 3 both an authorized distributor of record and a 4 wholesale distributor according to the code of 5 federal regulations? 6 A. You said 203.3D, the next page? 7 Q. Double D. 8 A. Double D. 9 Q. Do you see that? Do you want to read 10 that? 11 A. "Wholesale distributor means any 12 person engaged in the wholesale distribution of a 13 prescription drugs -- I beg your pardon -- 14 prescription drugs, including but not limited to 15 manufacturers, repackagers, own label distributors, 16 private label distributors, jobbers, brokers, 17 warehouse, including manufacturers and distributors' 18 warehouses, chain drug warehouses, and wholesale 19 drug warehouses, independent wholesale drug traders, 20 and retail pharmacies that conduct wholesale 21 distribution." 22 Q. Does that help you with respect to 23 understanding Mylan's role in this case? 24 A. No, it doesn't. I would have to -- 25 Q. Just yes or no.</p>	<p style="text-align: right;">Page 504</p> <p>1 talking about. I want you to show me in there where 2 it -- where it says that a wholesale distributor 3 must establish a quality agreement with a 4 manufacturer. 5 A. Okay. I would interpret -- 6 Q. Just show me the language that says a 7 wholesale distributor must establish a quality 8 agreement with a manufacturer. Just read the 9 language there. 10 A. It does not say -- use the word 11 quality agreement. 12 Q. Thank you. And that regulation that 13 you have before you which has been previously marked 14 I believe as exhibit -- 15 MS. CARTER: I think it's Plaintiff's 16 49. 17 BY MR. KAPLAN: 18 Q. Plaintiff's 49, is that included among 19 the documents that you relied upon in rendering your 20 opinions in this case which are contained in your 21 report of June 15, 2010? 22 A. Yes, it is. 23 Q. And where does that appear on the list 24 of references? 25 A. It's the second one, number two.</p>
<p style="text-align: right;">Page 503</p> <p>1 A. No, it does not. 2 Q. Are you aware of any regulation that 3 places a responsibility for compliance with 4 manufacturing GMPs on a wholesale distributor? 5 A. I'm not aware. 6 Q. Are you aware of any regulation that 7 requires wholesale distributors to establish quality 8 agreements with manufacturers or suppliers? 9 A. Regulation? I understand the certain 10 sections of the GMP and what the expectations and 11 requirements of the FDA are. 12 Q. Are you aware -- I'm going to ask you 13 the question again. Are you aware of any regulation 14 that requires wholesale distributors to establish 15 quality agreements with manufacturers? 16 A. Yes. 17 Q. Show me the -- 18 A. I would show you the paragraph 22 of 19 21011122 where it talks about quality systems, and I 20 would interpret that to -- 21 Q. Just -- just tell me what you refer 22 to, what you rely on? 23 A. I have to pull the GMP again. We 24 talked about it earlier. 25 Q. Give me -- give me the GMP that you're</p>	<p style="text-align: right;">Page 505</p> <p>1 Q. Okay. That cites the entire 21CFR 2 part 210 and 21CFR part 211. 3 A. Right. So I did not specify what 4 sections within that. 5 Q. And this is the precise regulation you 6 are relying upon, right? 7 A. That is correct. 8 Q. Which says nothing about a quality 9 agreement? 10 A. It does not use those words. 11 Q. Thank you. Are you aware of any 12 regulations that requires wholesale distributors to 13 audit manufacturing companies? 14 A. I'm aware of the requirements of GMP 15 which is to select, qualify, and monitor your 16 suppliers of which that would -- in Mylan's case 17 would include Actavis. 18 Q. Are you aware, I'm going to ask you 19 again, of any regulation that requires a wholesale 20 distributor to audit a manufacturing company? 21 A. Using those specific terms, no. 22 Q. Are you aware of any regulation or law 23 that gives wholesale distributors the right to 24 inspect manufacturers for CGMP compliance? 25 A. No.</p>

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<p style="text-align: right;">Page 506</p> <p>1 Q. Are you aware of any regulation that 2 requires a wholesale distributor to require a 3 certificate of analysis or certificate of 4 conformance from a manufacturer for finished 5 packaged product? 6 A. As stated, no. 7 Q. Are you aware of any regulation that 8 requires a wholesale distributor to perform periodic 9 chemical analysis of finished product purchased from 10 a manufacturer? 11 A. You're going to have to repeat that. 12 Q. Are you aware of any regulation that 13 requires a wholesale distributor to perform periodic 14 chemical analyses of finished product purchased from 15 a manufacturer? 16 A. In the regulations, it does not state 17 that specifically. 18 Q. Your final report in this case dated 19 June 15, 2010, previously marked as Exhibit 38, is a 20 lengthy one, isn't it? 21 A. It is the number of pages it is. 22 Q. The last numbered page is 50. Is that 23 correct? 24 A. Yes, it is. 25 Q. Less than a page of those 50 pages is</p>	<p style="text-align: right;">Page 508</p> <p>1 complaint handling, they needed to do it in 2 accordance to good manufacturing practice and in 3 cooperation with the manufacturer. 4 Q. So you've read the supply and 5 distribution agreement? 6 A. Yes. 7 Q. And -- and you agree with me that it 8 has provisions in there about complaint handling? 9 A. Yes, I believe it does. 10 Q. Whose responsibility do you think it 11 was to handle the complaints? 12 A. I'm sorry. 13 Q. Whose responsibility do you think it 14 was to handle the complaints? 15 A. Well, there's -- there's a lot of 16 functions associated with complaints. The -- the 17 receipt of the complaints, the records of the 18 complaints, would side in two spots. One would be 19 in Mylan and the other would be in Actavis. Actavis 20 would engage in investigation if requested by Mylan. 21 If they weren't aware of a complaint, they couldn't 22 investigate it. 23 Q. Can you tell me what part of the 24 agreement you're referring to? 25 A. I don't recall.</p>
<p style="text-align: right;">Page 507</p> <p>1 devoted to any discussion about Mylan, isn't it? 2 A. I believe that is correct, yes. 3 Q. You assumed that Mylan was the holder 4 of the ANDA? 5 A. No, I never assumed that. 6 Q. So you know that Mylan was not the 7 ANDA holder for DIGITEK? 8 A. That's correct, I knew that. 9 Q. And you know that Mylan was not the 10 manufacturer of DIGITEK? 11 A. They did not produce the product, 12 that's correct. 13 Q. Let me state it again. You know that 14 Mylan was not the manufacturer of DIGITEK? 15 A. That Mylan was not the manufacturer, 16 correct. 17 Q. Explain the basis for your assumption 18 that Mylan is required by GMP to investigate all 19 complaints as stated in -- on page 33 of your final 20 report dated June 15, 2010 previously marked as 21 Exhibit 38? 22 A. If I recall correctly, which I think I 23 do, the supply agreements stated that Mylan would 24 handle complaints which was a good thing that it was 25 stated. The -- since they took ownership of</p>	<p style="text-align: right;">Page 509</p> <p>1 Q. Do you want to take a look at it? 2 A. Sure. 3 Q. Why don't you do that. 4 A. I don't have the agreement here. 5 Q. Did you look at the supply and 6 distribution agreement? 7 A. Very early on. Yes. 8 Q. When did you last look at it? 9 A. It was probably one of the first 10 documents I looked at. 11 Q. How early in the process? 12 A. Very early. 13 Q. You told me just a few minutes ago 14 that when you drafted your initial report, you 15 didn't look at any Mylan documents? 16 A. I realized that I did afterwards. 17 Q. Have you misspoken yourself again? 18 A. Yes. I did look at it, I did see it. 19 Q. So when you -- when you drafted your 20 initial report and said nothing about Mylan, you had 21 already looked at the supply and distribution 22 agreement between Mylan and Actavis? 23 A. I had scanned through it. 24 Q. And when you -- when you drafted your 25 subsequent report, draft number two, you had looked</p>

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<p style="text-align: right;">Page 510</p> <p>1 at the supply and distribution agreement between 2 Mylan and Actavis? 3 A. I had scanned at it at the original 4 time. I didn't scan it again. 5 Q. And still offered no opinion as to 6 Mylan? 7 A. That's correct. 8 Q. What was your -- what was your great 9 revelation then that caused you to -- 10 A. I explained it earlier. I was asked 11 do I -- have I looked at the Mylan documents, and I 12 said, no, I have not looked at them. 13 Q. But now you just told me you had 14 looked at them? 15 A. Well, I looked at one document. I 16 don't remember where the supply agreement was. 17 Q. Maybe you had better rethink this 18 again because this is -- this is sworn testimony 19 that you're giving under oath, and I don't want you 20 to misspeak yourself. 21 A. I understand. 22 Q. You told me at the time that you 23 drafted the first two reports which led to the final 24 report? 25 A. Right.</p>	<p style="text-align: right;">Page 512</p> <p>1 in general and a supply agreement. 2 Q. It contains provisions such as the 3 fact that Actavis shall remain responsible for 4 maintaining and fulfilling all regulatory 5 requirements, doesn't it? 6 A. Uh-huh. That would be common 7 terminology used. 8 Q. It provides for procedures in 9 reporting adverse drug experience information, 10 doesn't it? 11 A. It says that, yeah. 12 Q. That's important, isn't it? 13 A. Important to whom? 14 Q. Well, important to you as expert in 15 this case offering opinions against Mylan. That's 16 important, isn't it? 17 A. Is it important -- it's referenced in 18 there, but it's not the -- it's not what I'm looking 19 for. I'm looking for substantive, specific 20 information as to who's responsible for what and 21 going down to on a day to day level. Who is doing 22 what. 23 Q. Well, how about this -- 24 A. Similar to the document that they 25 wrote, in other words, their draft is a reasonably</p>
<p style="text-align: right;">Page 511</p> <p>1 Q. You hadn't looked at Mylan documents. 2 Now you say you had looked at the supply and 3 distribution agreement. What's -- what's the 4 correct testimony here? 5 A. I saw that particular document and I 6 recall that I did review it. 7 Q. When did you see that document? 8 A. As I said, very early on in the 9 process. I looked at it, I blitzed through it, 10 because I was seeking a quality agreement, not the 11 general terms of operating between two companies. 12 Because the supply agreement has nothing to do with 13 the area that I'm expert in unless it includes the 14 quality agreement type requirements and -- and 15 specification of responsibilities. 16 Q. What criticisms do you have of the 17 supply and distribution agreement? 18 A. I have no criticism of it. I -- you 19 know, I scanned through it. I would have no opinion 20 on it, it's an operations document. It's focused as 21 an operations document. 22 Q. It's what? 23 A. It's an operations document. 24 Q. What does that mean? 25 A. Associated with terms, financial terms</p>	<p style="text-align: right;">Page 513</p> <p>1 comprehensive document. 2 Q. How about this: Do you recall that 3 the supply and distribution agreement between Mylan 4 and Actavis provides that Mylan shall refer or 5 submit to Actavis all drug experience reports and 6 other medical inquiries or quality complaints 7 associated with the products within 48 hours of 8 Mylan's receipt of such reports? 9 A. Okay. 10 Q. Do you recall that? 11 A. I don't recall it specifically, but I 12 remember there was a complaint. 13 Q. Is that an appropriate provision? 14 A. I believe so. 15 Q. It says all telephone calls shall be 16 referred to Actavis. Is that appropriate? 17 A. It a legal -- situation -- I would 18 have no expert opinion on that particular aspect of 19 it. 20 Q. You don't have any criticism of that, 21 do you? 22 A. I have no criticism of it. 23 Q. It says, "Actavis shall be responsible 24 for fulfilling any regulatory requirements with 25 respect to such events, including but not limited to</p>

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<p style="text-align: right;">Page 514</p> <p>1 the filing of all form FD 2253s, contact and 2 follow-up with the patient or reporter of the event 3 and will make any necessary contact with the FDA 4 regarding the subject matter of the same." 5 A. I'm not familiar with those terms. I 6 have no opinion on it. 7 Q. That places responsibility clearly on 8 the shoulders of Actavis, doesn't it? 9 A. I would have to study that further. 10 I'm not going to -- I don't think I can give an 11 opinion based upon reading one sentence out of a 12 supply agreement. 13 Q. The fact is you really haven't read 14 this supply agreement, have you? 15 A. I told you I scanned through it and I 16 looked for certain conditions which I did not find 17 in there. And the conditions that you're talking 18 about are not what I was not looking for. 19 Q. The supply and distribution agreement 20 between Actavis and Mylan provides that "Actavis 21 shall be responsible for filing and maintaining all 22 documentation and other information as required by 23 each and every state and locality for the purpose of 24 listing the products on each state's formulary or 25 other similar authority, and for obtaining such</p>	<p style="text-align: right;">Page 516</p> <p>1 Q. That places responsibility squarely on 2 the shoulders of Actavis, didn't it? 3 A. For that subject. 4 Q. The agreement further provides that 5 "Actavis shall provide the results of such tests to 6 Mylan in the form of a certificate of analysis." 7 Is that appropriate? 8 A. If they agree to it, certainly. 9 Q. What is a certificate of analysis? 10 A. The certificate of analysis is the 11 summary of all of the finished product testing 12 results. 13 Q. That's a good thing that the 14 certificate of analysis was being provided? 15 A. Absolutely. 16 Q. The supply and distribution agreement 17 between Mylan and Actavis dated August 5, 1999 18 provides that "Actavis will manufacture, package, 19 label, store, and ship the products," being DIGITEK, 20 that is the subject of the agreement. So Actavis 21 will "manufacture, package, label, store, and ship 22 DIGITEK in accordance with the specifications set 23 forth in the ANDA, and as such ANDA may be amended 24 from time to time." 25 Is that an appropriate provision in the</p>
<p style="text-align: right;">Page 515</p> <p>1 approvals as may be necessary to sell the products 2 in those states." 3 Is that an appropriate provision? 4 A. I don't know what is appropriate or 5 not appropriate. It's a regulatory legal issue, not 6 a GMP issue under the GMP category. 7 Q. The supply and distribution agreement 8 between Actavis and Mylan which is dated August 5, 9 1999, provides that Actavis grants to Mylan the 10 exclusive right to market, sell, and promote and 11 distribute products. Is that your understanding? 12 A. Yes, that is my understanding. 13 Q. Anything wrong with that? 14 A. I can't say whether it's wrong or 15 right. It just is. 16 Q. The supply and distribution agreement 17 dated August 5 1999 between Mylan and Actavis 18 provides that "Actavis shall perform quality 19 assurance testing with respect to the products sold 20 hereunder." That is DIGITEK. 21 A. Right. 22 Q. "Including stability testing so that 23 the products conform with the specifications." 24 Anything wrong with that? 25 A. No, not that I can see.</p>	<p style="text-align: right;">Page 517</p> <p>1 agreement? 2 A. It seems appropriate. 3 Q. Do you have any criticism of that? 4 A. I have no criticism. 5 Q. That seems to place responsibility 6 squarely on the shoulders of Actavis, doesn't it? 7 A. In that particular situation, yes. 8 Q. The agreement further provides that 9 "Mylan shall be promptly and fully advised of any 10 new instructions or specifications required by the 11 FDA or the FFDCA." 12 Is that appropriate? 13 A. I believe so. 14 Q. Further provides that "Mylan's quality 15 control personnel upon reasonable prior notice shall 16 be permitted to observe the manufacture of DIGITEK." 17 Is that appropriate? 18 A. Yes. 19 Q. Further provides that "in the event 20 Actavis cannot manufacture products in accordance 21 with the instructions and specifications, Actavis 22 shall promptly so advise Mylan." 23 Is that appropriate? 24 A. Yes. 25 Q. And further, that "Actavis shall not</p>

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<p style="text-align: right;">Page 518</p> <p>1 change any ANDA or specification without the prior 2 written consent of Mylan." Appropriate? 3 A. Appropriate. 4 Q. Good practice? 5 A. Appropriate. It is a must practice. 6 Q. The supply and distribution agreement 7 of August 5, 1999 between Actavis and Mylan further 8 provides that "Actavis will package and label 9 products under the Mylan name and Actavis shall 10 provide all finished labeling for the products in 11 accordance with any applicable FDA or other 12 regulatory labeling requirements." Appropriate 13 provision? 14 A. I have no expertise on the subject, 15 but it appears appropriate. 16 Q. Any criticism of that? 17 A. No criticism. 18 MS. CARTER: For the record, when 19 you're reading it, you're changing Amide to 20 Actavis and Bertek to Mylan. 21 MR. KAPLAN: I sure am. And we 22 established that before, and he agreed with 23 me that any references to Amide, we would 24 call Actavis and any references to Bertek we 25 would call Mylan.</p>	<p style="text-align: right;">Page 520</p> <p>1 Q. I move that that answer be stricken as 2 not responsive. 3 Do you cite the supply and distribution 4 agreement among the references that you relied upon? 5 A. No, I did not. 6 Q. Did the FDA ever criticize Mylan for 7 violating CGMP regulations relating to the 8 distribution of DIGITEK? 9 A. I'm not aware of any. 10 Q. Did the FDA ever criticize Mylan in 11 connection with its distribution of Digitek? 12 A. I'm not aware of any. 13 Q. Did the FDA ever criticize Mylan with 14 respect to the recall of DIGITEK? 15 A. I'm not aware of any. 16 Q. Did the FDA ever criticize Mylan 17 regarding the handling of DIGITEK related 18 complaints? 19 A. I'm not aware of any. 20 Q. Has the FDA ever criticized Mylan's 21 vendor management or supplier management policies? 22 A. Again, I have no way of knowing. 23 Q. Has the FDA ever criticized any other 24 distributor in connection with the events 25 surrounding the 2008 Actavis recalls?</p>
<p style="text-align: right;">Page 519</p> <p>1 A. And that is appreciated. 2 BY MR. KAPLAN: 3 Q. Okay. So this supply and distribution 4 agreement, which by the way, was previously marked 5 as Exhibit M1 at the deposition of Susie Wolf, which 6 is one of the depositions that you didn't read, is a 7 document that you scanned early on in your review 8 here, right? 9 A. That's correct. 10 Q. Before you ever wrote a draft report? 11 A. Before, I don't know whether I wrote 12 the draft report or started. When we're talking 13 about a draft report, we're talking about the 14 beginning of the graphs, the matrices. 15 Q. And you were aware of the supply and 16 distribution agreement and reviewed it before you 17 drafted your first report. That's what your 18 testimony was? 19 A. I don't recall. 20 Q. Now you don't recall? 21 A. No. Honestly, I'm not sure if I did 22 it before or after. I look at hundreds of 23 documents. I don't remember whether I read it 24 before or after. That's unfair to ask me that. I 25 mean, it's unfair to expect me to remember that.</p>	<p style="text-align: right;">Page 521</p> <p>1 A. I don't know how I would have that 2 information, so I don't -- I would say I haven't 3 seen anything. 4 THE VIDEOGRAPHER: We're off the 5 record. The time is 4:24. This is the end 6 of tape 4. 7 (Recess taken.) 8 THE VIDEOGRAPHER: We're back on the 9 record. The time is 4:38. This is the 10 beginning of tape 5. 11 BY MR. KAPLAN: 12 Q. All right. You would -- you would 13 agree that current good manufacturing practices 14 which is abbreviated CGMP, also referred to as GMP, 15 is a law that is established in the code of federal 16 regulations, right? 17 A. Yes. 18 Q. That's the law? 19 A. That's the law. 20 Q. And it sets standards for a product to 21 meet specific requirements for identity, strength, 22 quality, and purity, correct? 23 A. That's a portion of it, yes, that's 24 correct. 25 Q. And it's a law that outlines the</p>

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<p style="text-align: right;">Page 522</p> <p>1 requirements for every drug manufacturer to follow?</p> <p>2 A. That's correct.</p> <p>3 Q. That law has been continually improved</p> <p>4 over the years since it was first adopted?</p> <p>5 A. Slightly revised, but yes, it has</p> <p>6 been. Yes, it has been improved.</p> <p>7 Q. Has been continually improved?</p> <p>8 A. Yes, that's correct.</p> <p>9 Q. It's your opinion that the current</p> <p>10 good manufacturing practice regulations are well</p> <p>11 designed documents?</p> <p>12 A. That is correct.</p> <p>13 Q. The current good manufacturing</p> <p>14 practice regulations are a great help in ensuring</p> <p>15 that patients and customers receive 100 percent safe</p> <p>16 and effective drug products?</p> <p>17 A. Yes, that's correct.</p> <p>18 Q. And it's your experience that the FDA</p> <p>19 understands the business and fairly and impartially</p> <p>20 uses a heavy hand only when they fear public safety?</p> <p>21 A. That's correct.</p> <p>22 Q. And even in those high risk</p> <p>23 situations -- well, in those high risk situations,</p> <p>24 they continually escalate their concerns until all</p> <p>25 public risks are resolved?</p>	<p style="text-align: right;">Page 524</p> <p>1 Q. Well, let me read a portion to you.</p> <p>2 "Myth, there are quality problems with generic drug</p> <p>3 manufacturing. A recent recall of generic Digoxin,</p> <p>4 called DIGITEK, shows that generic drugs put</p> <p>5 patients at risk. Fact, FDA's aggressive action in</p> <p>6 this case demonstrates the high standards to which</p> <p>7 all prescription drugs, generic and brand name, are</p> <p>8 held."</p> <p>9 Would you agree with that?</p> <p>10 A. Can I read it again? I would rather</p> <p>11 read it than hear you say it. Can I read it,</p> <p>12 please?</p> <p>13 Q. I'm just asking whether you agree with</p> <p>14 that statement?</p> <p>15 A. I understand that. I would like to</p> <p>16 read it.</p> <p>17 Q. I'm going to ask the question and I</p> <p>18 would like you to answer it. "FDA's aggressive</p> <p>19 action in this case demonstrates the high standards</p> <p>20 to which all prescription drugs, generic and brand</p> <p>21 name, are held?"</p> <p>22 A. I would say I agree with that.</p> <p>23 Q. The FDA, you acknowledge, has an</p> <p>24 abiding interest in public safety?</p> <p>25 A. Most assuredly.</p>
<p style="text-align: right;">Page 523</p> <p>1 A. Yes, that is their objective.</p> <p>2 Q. And -- and that's what they did in the</p> <p>3 case of DIGITEK, in the DIGITEK recall, right?</p> <p>4 A. I -- certainly they work with Actavis</p> <p>5 and they escalated it to the point that you can't go</p> <p>6 any further other than criminal prosecution, as far</p> <p>7 as I could see.</p> <p>8 Q. Well, they escalated their concerns</p> <p>9 until all public risks were resolved?</p> <p>10 A. Right. Well put. Correct.</p> <p>11 Q. In fact, that's how you put it on page</p> <p>12 8 of your report of June 15, 2010, isn't it?</p> <p>13 A. Okay. If it says that. I don't have</p> <p>14 it in front of me.</p> <p>15 Q. It is what you said?</p> <p>16 A. Okay. I trust you.</p> <p>17 Q. And then the FDA, following the</p> <p>18 resolution of risks to public safety with regard to</p> <p>19 DIGITEK, published a document which is posted on the</p> <p>20 FDA Website on the Internet titled, "facts and myths</p> <p>21 about generic drugs."</p> <p>22 A. Yes.</p> <p>23 Q. And you are familiar with that</p> <p>24 document, aren't you?</p> <p>25 A. Reasonably familiar. I've read it.</p>	<p style="text-align: right;">Page 525</p> <p>1 Q. Said "since the detection of the</p> <p>2 manufacturing problem with DIGITEK, FDA has been</p> <p>3 actively engaged with Actavis to ensure that all</p> <p>4 potentially defective lots of DIGITEK have been</p> <p>5 recalled."</p> <p>6 Could you agree that they did that?</p> <p>7 A. They appear to have done that.</p> <p>8 Q. And then the FDA said, and continues</p> <p>9 to say in the document entitled, "facts and myths</p> <p>10 about generic drugs" posted on the FDA's Website,</p> <p>11 the FDA says, "In our best judgment, given the very</p> <p>12 small number of defective tablets, it may have</p> <p>13 reached the market. The lack of reported adverse</p> <p>14 events before the recall, harm to patients was very</p> <p>15 unlikely."</p> <p>16 A. I can't argue with that or -- I don't</p> <p>17 know what would harm a person. So the term "harm"</p> <p>18 takes it away from something I would have an opinion</p> <p>19 for.</p> <p>20 Q. In appendix F to your report of</p> <p>21 June 15, 2010, pages 47 through 50, the heading is,</p> <p>22 "FDA observations and events." You would agree with</p> <p>23 me that there is no mention of Mylan in there,</p> <p>24 correct?</p> <p>25 A. That is correct.</p>

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<p style="text-align: right;">Page 526</p> <p>1 Q. And you would agree with me that in 2 your final report dated June 15, 2010 on page 35 3 under the heading of "expert witness final summary," 4 there is no mention of Mylan? 5 A. There is no mention of Mylan. 6 Q. You would also agree with me that on 7 pages 5 and 6 of your final report dated June 15, 8 2010 under the heading, "introduction," there is no 9 mention of Mylan? 10 A. That is correct. 11 Q. And you would also agree with me that 12 on page 7 of your final report dated June 15, 2010 13 under the heading, "work plan," there is no mention 14 of Mylan? 15 A. That is correct. 16 MR. KAPLAN: Off the record. 17 THE VIDEOGRAPHER: We're off the 18 record the time is 4:48. 19 (Recess taken.) 20 THE VIDEOGRAPHER: We're back on the 21 record. The time is 5:03. 22 EXAMINATION BY MR. ANDERTON: 23 Q. Mr. Kenny, my name is Michael 24 Anderton. I'm here on behalf of the Actavis 25 defendants. We've met, correct?</p>	<p style="text-align: right;">Page 528</p> <p>1 documents that you brought with you today? 2 A. Yes. 3 Q. That weren't in this yellow folder? 4 A. Okay. 5 Q. And the yellow folder was marked 6 Exhibit 110? 7 A. Right. It was in another folder. 8 Q. Right. That's fine. I'm going to ask 9 you some questions about both groups, some e-mails 10 in both groups. This is a different stack. Do you 11 remember giving us this stack? 12 A. Yes. 13 Q. All right. And I'm looking now at -- 14 and eventually, we're going to leave this with the 15 court reporter and she'll make copies and we'll 16 all -- you'll get your back, or a copy back, at 17 least, and we'll all have a copy. But for now, we 18 don't have extra copies, all right? 19 A. Okay. 20 Q. I'm looking at an e-mail thread 21 that -- well, give me one second. Looking at an 22 e-mail thread -- or actually, a single page e-mail, 23 it starts on -- well, it's an e-mail thread. It 24 starts on February 19, an e-mail from Sandy Summers, 25 who is at Meghan Johnson's law firm, I believe she's</p>
<p style="text-align: right;">Page 527</p> <p>1 A. That's correct. 2 Q. All right. I'm going to ask you some 3 questions. We're going to cover some topics that 4 you've already cover with Mr. Kaplan, and perhaps 5 even some that we've covered a little bit in your 6 prior deposition session. I know Mr. Kaplan didn't 7 go over this, but just to kind of remind you, if I 8 ask you a question and you don't understand it, 9 please make sure that you let me know that. 10 A. Yes. 11 Q. So that you and I have an 12 understanding of what I'm asking and what you are 13 answering before you give an answer. Is that all 14 right? 15 A. Yes. 16 Q. Okay. So if you answer a question, I 17 will assume that you understood it. Is that fair? 18 A. Yes. 19 (Whereupon, Exhibit 143, E-mails, was 20 marked for identification as of today's 21 date.) 22 Q. All right. I am looking at a document 23 that has been marked as Exhibit 143, and it is a 24 stack of e-mails that you received -- I'm sorry -- 25 that you provided to us from your -- from the</p>	<p style="text-align: right;">Page 529</p> <p>1 a paralegal or a legal assistant of some type, 2 forwarding to you and Mr. Romano a confidentiality 3 order and a letter of engagement? 4 A. Right. 5 Q. Does that mean that your engagement 6 with or on behalf of the plaintiffs started sometime 7 right around February 19 of 2010? 8 A. I believe that's correct. 9 Q. Does that sound about right? 10 A. Yes. 11 Q. And then on the 23rd of February, 12 there's further e-mail communication from 13 Ms. Johnson to you about the protective order and 14 about sending you documents. Another e-mail in this 15 stack -- actually, again, an e-mail thread, is dated 16 February -- the first e-mail in the thread is dated 17 February 24, 2010, so about five days after you 18 received the engagement letter to undertake work for 19 the plaintiffs? 20 A. Okay. 21 Q. And according to this e-mail, it's 22 from Sal Romano to Meghan Johnson and a copy to 23 SpyGlass. I assume that you have access to that 24 e-mail box? 25 A. Yes.</p>

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<p style="text-align: right;">Page 530</p> <p>1 Q. Or the mail sent to that address?</p> <p>2 A. Yes, I have access to it.</p> <p>3 Q. And it says, "Mark and I have received</p> <p>4 the dots on the CD. Thanks. We will be traveling</p> <p>5 starting Friday until March 9. We intend to take</p> <p>6 the dots with us and review them on the trip."</p> <p>7 That means -- is that the first group of</p> <p>8 documents you would have received from the</p> <p>9 Plaintiff's counsel?</p> <p>10 A. Yes, that's correct. The disk which</p> <p>11 you -- you have.</p> <p>12 Q. Okay. So the first group of documents</p> <p>13 that you received was February 24, 2010?</p> <p>14 A. Correct.</p> <p>15 Q. And on that same day about an hour</p> <p>16 after you received an e-mail from Ms. Johnson, you</p> <p>17 responded to Ms. Johnson. Actually, you said to Sal</p> <p>18 in an e-mail, "the actual batch records are</p> <p>19 extremely important. Do you want me to request the</p> <p>20 information?" Do you remember making -- sending</p> <p>21 that e-mail?</p> <p>22 A. I don't remember, but I'm sure I put</p> <p>23 that down. No, I don't remember the e-mail.</p> <p>24 Q. All right. And within a matter of</p> <p>25 moments, Mr. Romano e-mailed Mrs. Johnson at 3:48 on</p>	<p style="text-align: right;">Page 532</p> <p>1 trip. I'm here for at least the next hour or so.</p> <p>2 Give me a call if you have a chance. Thanks."</p> <p>3 A. Right.</p> <p>4 Q. So she responded to your e-mail by</p> <p>5 essentially saying that's an awful lot, are you sure</p> <p>6 you want to read that; is that right?</p> <p>7 A. Yes, that's correct.</p> <p>8 Q. And she never did send you those batch</p> <p>9 records, did she?</p> <p>10 A. I don't think I ever saw them.</p> <p>11 Q. All right. So you asked for the batch</p> <p>12 records and identified them as absolutely critical,</p> <p>13 and the Plaintiff's counsel responded by saying we</p> <p>14 don't think you should review them?</p> <p>15 A. No, that's not what they said. What</p> <p>16 they said is we got a lot, if you want to see them,</p> <p>17 you know, we'll give them to you. And at that</p> <p>18 particular point, early on and in -- I don't know if</p> <p>19 you call it the discovery process, but of documents</p> <p>20 I would like to see, that was clearly one of those</p> <p>21 documents that I thought at that point I wanted to</p> <p>22 see.</p> <p>23 Q. And how -- and in fact -- well, how</p> <p>24 did it come to be that the batch records weren't</p> <p>25 critical?</p>
<p style="text-align: right;">Page 531</p> <p>1 February 24, the same day you got the first disk,</p> <p>2 and said, "Mark and I believe the batch records will</p> <p>3 be critical for us to review. How many batches were</p> <p>4 recalled? Do you have all the batch records as PDF</p> <p>5 files? We have lots to read now, but I think we'll</p> <p>6 have to take a look at the batch records soon.</p> <p>7 Thanks Sal." And your -- again, that SpyGlass</p> <p>8 e-mail address is copied on that document?</p> <p>9 A. I understand.</p> <p>10 Q. Do you remember Mr. Romano sending</p> <p>11 that e-mail?</p> <p>12 A. No, I don't but it makes sense. I</p> <p>13 mean I --</p> <p>14 Q. All right. So the first day that you</p> <p>15 got document from the plaintiff's counsel, you</p> <p>16 immediately responded and said we need to see the</p> <p>17 batch records?</p> <p>18 A. Correct.</p> <p>19 Q. And in response, Ms. Johnson says we</p> <p>20 have the batch records. She says later that day,</p> <p>21 and I'll just read it so that it's accurate. "I</p> <p>22 just got Mark's message and tried to call him back.</p> <p>23 We do have the batch records but there are</p> <p>24 approximately 170 plus batches for Digoxin. So</p> <p>25 that's quite a bit of paperwork for a review on your</p>	<p style="text-align: right;">Page 533</p> <p>1 A. When I do an audit, I'm looking for</p> <p>2 exceptions. I found so many exceptions in the three</p> <p>3 batches that I looked at I could make conclusions</p> <p>4 off of that. I couldn't make conclusions that every</p> <p>5 batch record was wrong, but I could make conclusions</p> <p>6 that the batch records that I reviewed demonstrated</p> <p>7 significant GMP issues.</p> <p>8 Q. For those batches?</p> <p>9 A. For those batches.</p> <p>10 Q. So you couldn't make any conclusions</p> <p>11 about any of the other batches?</p> <p>12 A. It would be difficult in general.</p> <p>13 Q. Let's talk about -- I guess I just</p> <p>14 want to make sure I have a clear understanding of</p> <p>15 the timing, and actually, just give me one second.</p> <p>16 I want to make sure that I have a clear</p> <p>17 understanding of the timing of Mr. Romano's</p> <p>18 involvement. Your testimony has been repeatedly</p> <p>19 that the original intention was that you and</p> <p>20 Mr. Romano were going to be jointly engaged both to</p> <p>21 draft the report and to testify, correct?</p> <p>22 A. That is correct.</p> <p>23 Q. And so that's how the engagement</p> <p>24 certainly started, right?</p> <p>25 A. Yes.</p>

59 (Pages 530 to 533)

<p style="text-align: right;">Page 534</p> <p>1 Q. And we see from the billing records 2 that Mr. Romano was billing substantive time on this 3 engagement beginning at the beginning of the 4 engagement in the February, March, April time frame, 5 and that continued all the way through June, 6 correct? 7 A. Correct. We started the same time 8 approximately. 9 Q. And in a -- now, this is where I'll 10 need you to take out the three versions of your 11 report that we've been talking about as exhibits and 12 kind of have them side by side. All right? You 13 have the final version that is I believe Exhibit 38, 14 as Mr. Kaplan identified that correctly? 15 MR. KAPLAN: I think it's actually 48. 16 THE WITNESS: I have my own copy, but 17 it's the same thing. 18 MR. KAPLAN: I do believe that the 19 exhibit -- that the final report dated 20 June 15, 2010 was previously marked as 21 Exhibit 48, and I probably misspoke myself. 22 MR. ANDERTON: More than once 23 probably. 24 MR. KAPLAN: Probably more than once. 25 So if the record can be corrected, I think</p>	<p style="text-align: right;">Page 536</p> <p>1 draft and testify? 2 A. Yes. 3 Q. And if you look at Exhibit 140 which 4 you believe is a draft prepared after -- 5 A. Right. 6 Q. -- Exhibit 141. And again, if you 7 look at -- one second. Page 5 of Exhibit 140, will 8 you look at that page, please? 9 A. 140, yes. 10 Q. You see that it also says -- still -- 11 still indicates that Mr. Romano will be 12 participating in drafting the report and testifying, 13 correct? 14 A. Correct. 15 Q. So this is sometime after May 26, 16 right? 17 A. Sometime after, I can't tell you when. 18 Q. Well, we know that you met plaintiff's 19 counsel in early June in person, right? 20 A. Early June? We met in New York City 21 in person. 22 Q. Sometime in early June? 23 A. I don't remember -- if I looked at -- 24 you know, my billing it will show. Also. 25 Q. Why don't you do that. You've got</p>
<p style="text-align: right;">Page 535</p> <p>1 it was Exhibit 48, and we can check that. 2 And the other thing where I think I misspoke 3 perhaps was on the exhibit "facts and myths 4 about generic drugs." I know that has been 5 previously marked, and I think that was 6 previously marked as Exhibit 38. 7 A. I have 141. 8 BY MR. ANDERTON: 9 Q. So although there was some confusion, 10 Mr. Kenny, about some of your earlier testimony, as 11 I understand your current testimony, it is that what 12 has been marked as Exhibit 141 was your first draft, 13 right? 14 A. I believe that is correct, yes. 15 Q. And we know from the fact that we got 16 this off of a CD that you gave us this morning that 17 this was identified by you as a May 26, 2010 draft? 18 A. Correct. 19 Q. So as of -- and in the -- on Page 2 of 20 this draft, it still clearly indicates that 21 Mr. Romano and you have been engaged to draft the 22 report and provide expert testimony, right? 23 A. That's correct. 24 Q. So as of May 26, we know he is still 25 actively engaged, and the intention is that he will</p>	<p style="text-align: right;">Page 537</p> <p>1 that, right? Let's figure out when you met with the 2 Plaintiff's counsel. You said there were two 3 meetings face-to-face, right? 4 A. Yes. 5 Q. Were those meetings after you had 6 already prepared a draft? 7 A. The first one was not. The second 8 one, I had started the document at that point. 9 Q. Okay. 10 A. I don't recall how far along that 11 document was. 12 Q. Why don't you look at your time and 13 see if you can figure out when you met with the 14 plaintiffs in person. 15 A. There was a meeting on May 5th. 16 May 5th, but I can't tell you if that was a phone 17 meeting or a physical meeting. I can't tell you 18 from this, so far. I can continue to try. 19 Q. Well, let's -- actually, let's try 20 this another way. I'm looking again at the 21 documents in Exhibit 143, one of which is an e-mail 22 dated May 28, 2010 from Ms. Johnson to both you and 23 to that SpyGlass e-mail address, talking about a 24 Friday morning, June 4 meeting at the Newark 25 airport?</p>

60 (Pages 534 to 537)

<p style="text-align: right;">Page 538</p> <p>1 A. Newark airport, yes.</p> <p>2 Q. Does that make it seem likely that you</p> <p>3 met with Plaintiff's counsel in-person at the Newark</p> <p>4 airport?</p> <p>5 A. I did.</p> <p>6 Q. On June 4th?</p> <p>7 A. June 4th, if it says that, yes.</p> <p>8 Q. Okay. And Mr. Romano attended that</p> <p>9 meeting, right?</p> <p>10 A. That's correct.</p> <p>11 Q. And as we understand from Mr. Romano's</p> <p>12 earlier -- from something we saw earlier, an e-mail</p> <p>13 from Mr. Romano to plaintiff's counsel, part of the</p> <p>14 discussion at that June 4th meeting was to talk</p> <p>15 about strategy, right?</p> <p>16 A. That's correct.</p> <p>17 Q. And --</p> <p>18 A. What Sal referred to as strategy.</p> <p>19 Q. Okay.</p> <p>20 A. In using his terms. To me it was a</p> <p>21 status check, where are we, you know, what's the</p> <p>22 next step.</p> <p>23 Q. Well, this -- this document that is</p> <p>24 marked as Exhibit 140 that is a draft that contains</p> <p>25 handwritten notes, your handwritten notes, that you</p>	<p style="text-align: right;">Page 540</p> <p>1 A. We had a draft there. The draft was</p> <p>2 scanned over about a 30 second period by Mike.</p> <p>3 Meghan did not see the draft. That was -- that was</p> <p>4 the extent of his review of that document. So he</p> <p>5 did see it, but he saw it in terms of format. I</p> <p>6 don't know if he could have read it in 30 seconds.</p> <p>7 Q. You mentioned a moment ago that you</p> <p>8 and Mr. Romano were having difficulties with the</p> <p>9 Crivella database. That's some sort of hosting</p> <p>10 environment where the plaintiffs hosted various</p> <p>11 documents and they made them available to you and</p> <p>12 Mr. Romano?</p> <p>13 A. That's correct.</p> <p>14 Q. So as of June 4 when you met with</p> <p>15 plaintiff's counsel, you and Mr. Romano, you were</p> <p>16 both still accessing and reviewing documents on the</p> <p>17 database?</p> <p>18 A. We were accessing documents, yes.</p> <p>19 Q. And reviewing them?</p> <p>20 A. Reviewing, sure.</p> <p>21 Q. Including Mr. Romano?</p> <p>22 A. He was still doing it. To a lesser</p> <p>23 extent -- I don't remember if he was doing it or</p> <p>24 not, to be honest with you. I was. I was.</p> <p>25 Q. You said -- I mean, the record will</p>
<p style="text-align: right;">Page 539</p> <p>1 now have acknowledged or that you previously</p> <p>2 acknowledged and today forgot and now have</p> <p>3 reaffirmed, reflect at least some comments of the</p> <p>4 Plaintiff's counsel. Did you have that draft with</p> <p>5 you at that June 4th meeting?</p> <p>6 A. I had a draft with me at the June 4th</p> <p>7 meeting, yes, I did.</p> <p>8 Q. And did you discuss that draft with</p> <p>9 the Plaintiff's counsel at that June 4th meeting?</p> <p>10 A. In principle, we discussed it.</p> <p>11 Q. What do you mean by "in principle"?</p> <p>12 A. Principle. Well, what are your</p> <p>13 findings? Did you look at XYZ, did you look at all</p> <p>14 the attachments associated with -- because I was</p> <p>15 having a lot of problems, as was Sal, with the</p> <p>16 Crivella database. It's very hard to navigate. So</p> <p>17 you find out later that there are documents in it</p> <p>18 that you didn't realize were in it. And so -- so</p> <p>19 there were questions as to did we review certain</p> <p>20 information. That was the -- yes. That was the</p> <p>21 conversation.</p> <p>22 Q. And plaintiffs had seen a draft at</p> <p>23 that time, right?</p> <p>24 A. They did not see a draft at that time.</p> <p>25 Q. When did they first see a draft?</p>	<p style="text-align: right;">Page 541</p> <p>1 show what you said a moment ago, Mr. Kenny, but your</p> <p>2 testimony not three moments ago was that both you</p> <p>3 and Mr. Romano were having difficulty accessing</p> <p>4 documents.</p> <p>5 A. That's correct.</p> <p>6 Q. You wouldn't have difficulty accessing</p> <p>7 if you weren't trying, right?</p> <p>8 A. Right. That's a good point.</p> <p>9 Q. So the handwritten notes on Exhibit</p> <p>10 140, I believe you also said early, as you responded</p> <p>11 to questions by Mr. Kaplan, that those notes</p> <p>12 reflected, at least in part, comments or thoughts</p> <p>13 inquiring about whether you had reviewed certain</p> <p>14 documents, right?</p> <p>15 A. Could you repeat that? Please repeat</p> <p>16 the question.</p> <p>17 Q. Could you read that back, please?</p> <p>18 (Record read.)</p> <p>19 A. That was a portion of that discussion.</p> <p>20 Q. Well, I want to be clear, now. The</p> <p>21 notes that --</p> <p>22 A. Oh, do you mean the notes that are on</p> <p>23 here, did they reflect the conversation that I had</p> <p>24 that talked about the documents, the additional</p> <p>25 documents that I should review or look at? It does</p>

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Mark Kenny, Volume II

Videotaped

February 16, 2011

<p style="text-align: right;">Page 542</p> <p>1 not include that.</p> <p>2 Q. I want to just make sure this part is</p> <p>3 clear, okay?</p> <p>4 A. All right.</p> <p>5 Q. You answered some questions by</p> <p>6 Mr. Kaplan about these notes earlier. And the</p> <p>7 record will show what your answers were. To the</p> <p>8 best of my recollection, one of the things you --</p> <p>9 one of the characterizations that you gave to these</p> <p>10 handwritten notes on Exhibit 140 is that they</p> <p>11 reflected, at least in part, your notes about</p> <p>12 comments that Plaintiff's counsel had made where</p> <p>13 they were asking you if you had reviewed certain</p> <p>14 documents or certain categories of documents. Do</p> <p>15 you remember giving that testimony?</p> <p>16 A. Yes, I do.</p> <p>17 Q. Okay. And that is the same type of</p> <p>18 discussion that you had at that June 4th meeting</p> <p>19 with Plaintiff's counsel, right?</p> <p>20 A. Yes, but it's hard to remember.</p> <p>21 Q. Well, you now said yes twice that that</p> <p>22 is one of the things that you discussed at that</p> <p>23 meeting?</p> <p>24 A. The content, yes. What was in the</p> <p>25 content, most definitely.</p>	<p style="text-align: right;">Page 544</p> <p>1 participate in drafting the report and to testify?</p> <p>2 A. I think it was his intention.</p> <p>3 Q. And so actually, your testimony was</p> <p>4 that the reason it was ultimately decided that he --</p> <p>5 Mr. Romano would not participate to that degree is</p> <p>6 because he had a conflict with his schedule and</p> <p>7 would have been the commitments of the litigation if</p> <p>8 he had participated to that extent, correct?</p> <p>9 A. That's what he said.</p> <p>10 Q. Well, is that -- is that your</p> <p>11 understanding of what happened?</p> <p>12 A. That's what he told me. I have no</p> <p>13 reason to question him.</p> <p>14 Q. So then but for those scheduling</p> <p>15 conflicts, he would have stayed on the report and</p> <p>16 testified, right?</p> <p>17 A. I don't know that he would have.</p> <p>18 Q. Well, are you aware of any other</p> <p>19 reason why he didn't, other than the scheduling</p> <p>20 conflicts?</p> <p>21 A. I think he -- yes, I think he had cold</p> <p>22 feet.</p> <p>23 Q. Cold feet?</p> <p>24 A. Yes. I think that he did not want to</p> <p>25 ultimately appear in a court case. That's what I</p>
<p style="text-align: right;">Page 543</p> <p>1 Q. Okay. And does that make you more</p> <p>2 able to tell whether the handwritten notes that you</p> <p>3 put on this copy were made at the June 4th meeting</p> <p>4 that you had with Plaintiff's counsel?</p> <p>5 A. I don't think these were made at that.</p> <p>6 I believe these were made between Sal and I. In my</p> <p>7 house.</p> <p>8 Q. Well, but you've already testified,</p> <p>9 Mr. Kenny, multiple times, that these notes reflect</p> <p>10 at least in part, comments made by Plaintiff's</p> <p>11 counsel. You said that in your last deposition and</p> <p>12 then you reaffirmed it after Mr. Kaplan pointed out</p> <p>13 to you that you had overlooked that prior testimony.</p> <p>14 So?</p> <p>15 A. The reality is it's hard for me to</p> <p>16 remember. I'm trying to put this thing together as</p> <p>17 to what document I had, what did I write on down. I</p> <p>18 don't remember. That's why -- and when I'm, let's</p> <p>19 say refreshed, if you will, by prior testimony, it's</p> <p>20 not coming together, I can't -- I can't tell you</p> <p>21 with certainty regarding those conversations.</p> <p>22 Q. Well, but as of June 4, Mr. Romano was</p> <p>23 still attending meetings with Plaintiff's counsel?</p> <p>24 A. That's correct.</p> <p>25 Q. And it was still his intention to</p>	<p style="text-align: right;">Page 545</p> <p>1 sensed.</p> <p>2 Q. That's what you sensed. Did he say</p> <p>3 that to you?</p> <p>4 A. No.</p> <p>5 Q. When -- when was the decision made?</p> <p>6 A. I don't know. I really don't know.</p> <p>7 Q. But it was made after June 4 and</p> <p>8 before June 15 when you finalized the report, right?</p> <p>9 A. Not necessarily, no. It could have</p> <p>10 happened before that.</p> <p>11 Q. How much before that?</p> <p>12 A. Oh, it would have been a week or so</p> <p>13 before.</p> <p>14 Q. A week or so before what?</p> <p>15 A. The June 4th. So it would have been</p> <p>16 the end of May, beginning of June, somewhere around</p> <p>17 there, where he determined that it didn't look like</p> <p>18 he look -- he looked at his calendar, he's going to</p> <p>19 Florida, XYZ. And he said I can't do this.</p> <p>20 Q. Did you discuss that at the meeting</p> <p>21 with Plaintiff's counsel at June 4?</p> <p>22 A. We discussed that. I don't know if it</p> <p>23 was discussed at June 4th. I don't know.</p> <p>24 Q. Was it resolved by that meeting?</p> <p>25 A. I don't remember. It might have been.</p>

62 (Pages 542 to 545)

<p style="text-align: right;">Page 546</p> <p>1 Q. Okay. But we know that we have a 2 May 26 draft and we have a draft that we know is 3 after May 26? 4 A. Right. 5 Q. And what we know is that in both of 6 those drafts, so at least one draft after May 26, 7 Mr. Romano is still indicated as part drafter and 8 somebody who will testify? 9 A. Well, I didn't take his name out, but 10 it was -- he was still as of May 25th, 26th, still 11 the intention was that this was would be a draft, a 12 report signed by both of us. 13 Q. Okay. And when -- now, let's look at 14 exhibit -- give me one second. Let's look at 15 Exhibit 141, which again, you've identified as the 16 first draft of your report. And turn to page 16, 17 please. 18 A. Sixteen. 19 Q. Yes. I want to ask you some more 20 questions about the bullet points that Mr. Kaplan 21 asked you about earlier. And first, with respect to 22 the parenthetical, the first one under the "overall 23 observations" heading. Do you see that 24 parenthetical? 25 A. Yes.</p>	<p style="text-align: right;">Page 548</p> <p>1 A. Yes, he is. 2 Q. And so when you say you were the one 3 who was going to testify, that's not true as of the 4 time of this draft, is it? 5 A. It is true somewhere in June. 6 MS. CARTER: Objection. 7 A. I don't know when that decision was 8 made, I honestly don't. 9 BY MR. ANDERTON: 10 Q. Well, but -- 11 A. It was a point where it became clear 12 that he was not going to testify. He did -- how he 13 communicated that, I don't recall, and when did he 14 communicate it. 15 Q. Well, speaking of communicating, we 16 now know that Plaintiff's counsel, Ms. Johnson, 17 Mr. Miller, et cetera, received a draft of your 18 report, correct? 19 A. They received it in a very late stage 20 report in June. 21 Q. How? How did they get it? 22 A. I sent it via -- did I fax it or 23 e-mail it? It was either faxed or e-mailed. I 24 don't recall. 25 Q. I have looked through the documents</p>
<p style="text-align: right;">Page 547</p> <p>1 Q. It says, "Mark, we need to write a 2 dialogue followed by bullet points on the 3 following." You said those are Mr. Romano's 4 comments, right? 5 A. Those are his comments. 6 Q. And he's telling you what to add to 7 the report, right? 8 A. He's making a suggestion. 9 Q. Well, it's not a suggestion; he's 10 telling you what to add to the report? 11 MS. CARTER: Objection. 12 BY MR. ANDERTON: 13 Q. Isn't it? 14 A. He's telling me whether or not I 15 accept them is another story. He's telling me to 16 add these to the report. He feels it's substantive. 17 Q. And you said, you know, you keep 18 wanting to say that this is solely your report? 19 A. Yes. 20 Q. But as of June -- as of sometime after 21 May 26th, which is three months plus into the 22 process and within two and a half or three weeks 23 before the report is due, he is still being 24 indicated as a drafter and as somebody who is going 25 to testify?</p>	<p style="text-align: right;">Page 549</p> <p>1 that you produced that you have represented as the 2 communications between you and Plaintiff's counsel. 3 There is no transmittal cover e-mail or other 4 document indicating that you are transmitting a 5 draft or a copy of your draft report to Plaintiff's 6 counsel. 7 A. I understand. 8 Q. Did you overlook that? 9 A. No. It was done at the Jersey Shore. 10 We were on vacation and I -- Denise handled it, and 11 I believe it was faxed. I'm going to guess it was 12 faxed, but there was no intent to hide any 13 documents. 14 Q. Who did you go to the Jersey Shore 15 with? 16 A. My wife. 17 Q. How long were you there? 18 A. We were there probably a week or so. 19 Q. When? 20 A. Somewhere around Memorial Day. 21 Q. After or before? 22 A. After or before what? 23 Q. Memorial Day? 24 A. I have to pull my calendar. We have a 25 house down there, we go down there regularly.</p>

<p style="text-align: right;">Page 550</p> <p>1 Q. I'm just trying to establish when you 2 were at the Jersey Shore. When did you take your 3 vacation to the Jersey Shore in 2010? 4 A. I don't recall. We took -- it's not a 5 vacation. We go down there for a couple of days. 6 When you're consulting, you go whenever you want, 7 you're off, you go down. I went down there 15 8 times. There is nothing remarkable. 9 Q. Okay. But it was sometime around 10 Memorial Day? 11 A. Correct. 12 Q. Which is before June 4? 13 A. Yes. 14 Q. So Plaintiffs had that draft before 15 you met with them in person on June 4? 16 A. They had them -- wait a minute, wait a 17 minute. I think I'm screwing this thing up. 18 MS. CARTER: Just take your time. 19 A. On June 4th -- on June 4th, I had a 20 copy, I can't tell you exactly which copy. Of which 21 is the one that Mike -- scanned. 22 BY MR. ANDERTON: 23 Q. Mike who? 24 A. I'm losing it here. Pete Miller. I'm 25 sorry. Pete Miller scanned. I don't know what copy</p>	<p style="text-align: right;">Page 552</p> <p>1 of it. Meghan got back to me and said -- had some 2 specifics, you know, some grammar kind of stuff, and 3 I believe Pete got back to me and questioned, either 4 questioned it before or at that point, about had I 5 looked at Mylan documents. I don't recall if it was 6 that or earlier. 7 Q. When Meghan got back to you, was 8 that -- how did she do that? 9 A. Meghan got back to me, we talked over 10 the phone. 11 Q. But you e-mailed them a copy of the 12 draft? 13 A. Yes, I did. 14 Q. All right. Again, I don't see that 15 e-mail in any of the e-mails that you provided? 16 A. I did my best to make copies of 17 everything. 18 Q. If I ask you to look again for the -- 19 specifically for any e-mail whereby you transmitted 20 drafts to the Plaintiff's counsel, will you do that? 21 A. Sure. 22 Q. All right. So you'll do that sometime 23 in the next several days and follow-up with 24 Plaintiff's counsel and let them know whether you 25 come up with anything?</p>
<p style="text-align: right;">Page 551</p> <p>1 that was, and he looked at it and then asked me a 2 couple of questions. He did not focus on it, he 3 didn't read it. He went like two seconds, two 4 seconds, two seconds (indicating). That's it. 5 Q. Are you saying he had his own copy or 6 he looked at your copy? 7 A. No. He would never saw a copy. I had 8 a copy. 9 Q. Mr. Kenny, you just told me that you 10 faxed or e-mailed a copy to the Plaintiff's counsel? 11 A. I e-mailed a copy. 12 Q. From the Jersey Shore sometime around 13 Memorial Day. June 4 is after Memorial Day. 14 MS. CARTER: Objection. 15 A. Yeah. 16 BY MR. ANDERTON: 17 Q. And now you are saying he never had a 18 copy. I'm confused. 19 A. Mike, I don't remember. The reality is 20 I don't remember the exchange, other than if I had 21 to sit there and say what was I sure of, I was sure 22 that I brought a copy to Newark airport. He took a 23 look at it, 30 seconds, on or about four days before 24 the finalization of that report. I sent a copy, I 25 guess it was via e-mail to Meghan. Pete got a copy</p>	<p style="text-align: right;">Page 553</p> <p>1 A. Sure. 2 Q. If you need to make a note, please do. 3 A. I am going to make a note. 4 Q. All right. Take your time. 5 A. Okay. Got it. 6 Q. So again, and again, the record will 7 reflect -- you know, your testimony will be 8 reflected in the transcript. When you were 9 discussing with Mr. Kaplan Exhibit 140 and your 10 characterization of whether these bullet points on 11 page 16 were substantive input from Mr. Romano or 12 whether you considered them and accepted them only 13 if you felt they were appropriate, you said you were 14 the one who was going to testify. But as of this 15 draft, that's not true, is it? 16 A. It probably is not true. It appears 17 not to be true. 18 Q. Okay. And in fact, as of the next 19 draft, Exhibit 141, whenever that was, sometime 20 after May 26, it's still not true, right? 21 A. I don't recall. 22 Q. Well, the document says -- 23 A. I understand that. 24 Q. -- that he's going to testify and 25 identifies him as a drafter, right?</p>

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<p style="text-align: right;">Page 554</p> <p>1 A. It most certainly does.</p> <p>2 Q. Okay. And go down further on page 16.</p> <p>3 The second parenthetical from Mr. Romano, and I'm</p> <p>4 going to read the beginning of it, it says, "Mark, I</p> <p>5 have added your stuff on GMP. Please add some</p> <p>6 dialogue." So he actually was adding things to the</p> <p>7 report apparently?</p> <p>8 A. He was next to me when we met, and he</p> <p>9 would -- I would give him a copy, he would -- he</p> <p>10 once, I believe only once, took the copy. He said</p> <p>11 you do your thing, work with Crivella, read</p> <p>12 documents. I'll do my thing. Take a look at this</p> <p>13 thing, try to organize it. I had some of my own</p> <p>14 thoughts, and ultimately, it came to this of which I</p> <p>15 took this and then without his assistance, edited it</p> <p>16 to what my opinion was.</p> <p>17 Q. He says here he added stuff to the</p> <p>18 report, his language?</p> <p>19 A. No. He added my stuff. In other</p> <p>20 words, it wasn't taken out -- I don't know what he</p> <p>21 meant by it, to be honest with you.</p> <p>22 Q. Wait a minute. You're drafting a</p> <p>23 document?</p> <p>24 A. Yes.</p> <p>25 Q. And he says I have added your stuff on</p>	<p style="text-align: right;">Page 556</p> <p>1 Q. You see the heading and then the first</p> <p>2 full bullet point under the heading. The heading</p> <p>3 reads, "Ineffective and unreliable methods," and</p> <p>4 continues on from there. Do you see that heading?</p> <p>5 A. Yes.</p> <p>6 Q. And do you see the first bullet point</p> <p>7 paragraph under that?</p> <p>8 A. Yes.</p> <p>9 Q. In that paragraph, you do an analysis</p> <p>10 and make a comment on the reliability of visual</p> <p>11 inspection.</p> <p>12 Do you see that?</p> <p>13 A. I do see that.</p> <p>14 Q. And you actually gave testimony about</p> <p>15 that in your earlier -- excuse me -- on June 29th at</p> <p>16 your prior deposition session. Do you remember</p> <p>17 that?</p> <p>18 A. Yes.</p> <p>19 Q. In this draft, you say that in your</p> <p>20 opinion, visual inspection is only 80 percent</p> <p>21 effective. Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. That is actually consistent with what</p> <p>24 you testified to on June 29. Do you remember that?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 555</p> <p>1 GMP and you don't even know what that means?</p> <p>2 A. Actually, I believe -- yeah, it means</p> <p>3 the attachments I believe. I'm trying to recreate</p> <p>4 this. Yes, it's the attachments, and that there was</p> <p>5 no dialogue associated with the attachments. That</p> <p>6 was his opinion. I don't recall if I ever did</p> <p>7 anything about it.</p> <p>8 Q. He then goes on to say, "I think the</p> <p>9 following section on DIGITEK is good. Can you get</p> <p>10 this section in the same bullet format?" Again,</p> <p>11 adding substantive input to the report, right?</p> <p>12 A. That's -- that is purely format, sir,</p> <p>13 purely format. He liked the bullet approach.</p> <p>14 That's all.</p> <p>15 Q. Go back to page 13 of Exhibit 141,</p> <p>16 please.</p> <p>17 A. Page 13?</p> <p>18 Q. Please.</p> <p>19 A. Yes.</p> <p>20 Q. And again, we know that this is</p> <p>21 according to your testimony, your first draft,</p> <p>22 right?</p> <p>23 A. This is, yeah, my first draft.</p> <p>24 Q. You see --</p> <p>25 A. But it's -- I'm sorry. Go ahead, sir.</p>	<p style="text-align: right;">Page 557</p> <p>1 Q. In this draft, however, you actually</p> <p>2 do a calculation and say that on the basis of your</p> <p>3 position, you believe there are five double thick</p> <p>4 tablets that weren't found, and that in your</p> <p>5 opinion, apparently went undetected when the batch</p> <p>6 was released. Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. So you actually at one point</p> <p>9 formulated an opinion about exactly how many double</p> <p>10 thick tablets you thought were still out there but</p> <p>11 undetected?</p> <p>12 A. I -- no. This is not -- this is --</p> <p>13 Sal put that in there, not me.</p> <p>14 Q. Sal put that in there?</p> <p>15 A. Yes. When we were sitting down, he's</p> <p>16 going through it, and he added stuff that -- that's</p> <p>17 why when I see check this math -- let me reread it</p> <p>18 again, please, because I did do some calculations.</p> <p>19 I think I wrote that. I think I wrote that.</p> <p>20 Q. So then let's have the reporter please</p> <p>21 read back the question I asked prior to that, I want</p> <p>22 you to answer what question, please.</p> <p>23 (Record read.)</p> <p>24 A. No, I did not form an opinion. I</p> <p>25 somehow did some math which doesn't even look</p>

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<p style="text-align: right;">Page 558</p> <p>1 correct.</p> <p>2 Q. Well, but you wrote this in your</p> <p>3 expert witness report, right?</p> <p>4 A. Expert witness report which was</p> <p>5 something that I was continually working on.</p> <p>6 Q. But you did a calculation --</p> <p>7 A. I calculated other things in there --</p> <p>8 I don't even remember the calculation. It doesn't</p> <p>9 even look like it could be anywhere near correct. I</p> <p>10 guess if you take the 80/20 rule.</p> <p>11 Q. So it would be correct then?</p> <p>12 A. If you -- yeah -- it would be correct</p> <p>13 what?</p> <p>14 Q. If you properly applied your theory,</p> <p>15 then the result of five defective tablets would be</p> <p>16 correct?</p> <p>17 A. Yeah. It's a flawed theory.</p> <p>18 Q. It's a flawed theory, the 80/20 rule?</p> <p>19 A. No, that therefore five would still</p> <p>20 remain. This is a statistical approach that five is</p> <p>21 just an extrapolated number which is I guess</p> <p>22 20 percent -- 20 plus percent of 20.</p> <p>23 Q. So but it's a flawed theory?</p> <p>24 A. The theory, yeah, I would not say that</p> <p>25 five remained in the market. I have no idea how</p>	<p style="text-align: right;">Page 560</p> <p>1 earlier today that we marked. And again, I don't</p> <p>2 have extra copies. I'm looking at an e-mail that is</p> <p>3 a two page e-mail, and again, it's an e-mail thread</p> <p>4 with a series of e-mails that relate to scheduling.</p> <p>5 And it looks as though in the first e-mail,</p> <p>6 Ms. Johnson asked you and Mr. Romano whether you're</p> <p>7 available for a call the next day and the date of</p> <p>8 Ms. Johnson's e-mail is June 8, 2010?</p> <p>9 A. Okay.</p> <p>10 Q. In response the following morning --</p> <p>11 I'm sorry, later that day, you respond and say</p> <p>12 you're available after 1:00 p.m., and the following</p> <p>13 morning early, Mr. Romano responds and says he's</p> <p>14 available until about 3:30 for a call. And then</p> <p>15 there are further e-mails apparently setting the</p> <p>16 call for 2 o'clock on June 9, 2010. Do you remember</p> <p>17 that telephone call?</p> <p>18 A. No.</p> <p>19 Q. Any reason to believe that it didn't</p> <p>20 happen?</p> <p>21 A. No reason to believe that it didn't</p> <p>22 happen.</p> <p>23 Q. All right. That's five days before</p> <p>24 your report was finalized?</p> <p>25 A. Okay.</p>
<p style="text-align: right;">Page 559</p> <p>1 much would have remained in the market. I have no</p> <p>2 idea.</p> <p>3 Q. And in your final report, that fact</p> <p>4 came out, right, it wasn't in your final report?</p> <p>5 A. That's correct.</p> <p>6 Q. Why?</p> <p>7 A. Because it's -- it shouldn't have been</p> <p>8 in there in the first place. It's nonsense.</p> <p>9 Q. It's nonsense? Did you discuss that</p> <p>10 calculation with Plaintiff's counsel.</p> <p>11 A. No. No. I don't recall ever, no.</p> <p>12 Q. Well, Mr. --</p> <p>13 A. No, no, no. Let me back up. I did</p> <p>14 not -- can I answer it? No, I did never discuss</p> <p>15 this with Plaintiff's counsel. No.</p> <p>16 Q. I guess I should caution you about</p> <p>17 being so definitive in your testimony since on more</p> <p>18 than one occasion today, we've learned that some of</p> <p>19 your fairly definitive testimony has been a little</p> <p>20 quick in terms of your thinking through it and how</p> <p>21 accurate it is. So, but you're certain then that</p> <p>22 you didn't discuss this with Plaintiff's counsel?</p> <p>23 A. Correct.</p> <p>24 Q. I'm also looking at, and I'm back in</p> <p>25 Exhibit 110, the folder of e-mails that you produced</p>	<p style="text-align: right;">Page 561</p> <p>1 Q. Right?</p> <p>2 A. Yes.</p> <p>3 Q. I'm sorry, six days. Now I'm not</p> <p>4 doing math so well. Mr. Romano is still</p> <p>5 participating in the discussions about the report?</p> <p>6 A. He's still participating in</p> <p>7 discussions, yes.</p> <p>8 Q. Okay. That's not so he can proofread</p> <p>9 it, is it?</p> <p>10 MS. CARTER: Objection.</p> <p>11 A. I don't know what his objectives are.</p> <p>12 BY MR. ANDERTON:</p> <p>13 Q. Okay. And the next day, I'm looking</p> <p>14 at another e-mail dated June 10, 2010, and in the</p> <p>15 original e-mail -- well, in this e-mail, Ms. Johnson</p> <p>16 forwards to you as well to the SpyGlass e-mail</p> <p>17 address, and to Saljromano@aol.com, a copy of a</p> <p>18 Mylan deposition that "discusses the audits of</p> <p>19 Actavis and frequency." Now, there's comments in</p> <p>20 your final report about the frequency of the audits</p> <p>21 conducted by Mylan on Actavis, aren't there?</p> <p>22 A. Yes.</p> <p>23 Q. And that happens to be one of the</p> <p>24 bullet points in your initial draft that Sal</p> <p>25 suggested you add to the final version, right?</p>

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<p style="text-align: right;">Page 562</p> <p>1 A. I believe that's accurate.</p> <p>2 Q. So and that is Exhibit 141 that we've</p> <p>3 talked about here over the last few minutes?</p> <p>4 A. Yes.</p> <p>5 Q. So here we are on June 10 and</p> <p>6 Ms. Johnson is sending to you and Mr. Romano Mylan</p> <p>7 deposition transcripts for your review and analysis,</p> <p>8 right?</p> <p>9 A. Right. Yes.</p> <p>10 Q. So Mr. Romano is still involved in</p> <p>11 analyzing records for the purpose of continued</p> <p>12 preparation of the report?</p> <p>13 A. No. At that point, Sal basically</p> <p>14 reviewed nothing.</p> <p>15 Q. Why is he getting copies of the</p> <p>16 transcript?</p> <p>17 A. Out of respect. The fact that he's</p> <p>18 still part of the project.</p> <p>19 Q. So he suggests on -- sometime on or</p> <p>20 about May 26 that you add comments in your report</p> <p>21 about Mylan's audit practice with respect to</p> <p>22 Actavis?</p> <p>23 MS. CARTER: Objection.</p> <p>24 BY MR. ANDERTON:</p> <p>25 Q. And two weeks later, you guys receive</p>	<p style="text-align: right;">Page 564</p> <p>1 that you don't provide time or date detail?</p> <p>2 A. I provide what I provide.</p> <p>3 Q. So the answer to my question is?</p> <p>4 A. Well, I have to look at the specifics.</p> <p>5 I have dates.</p> <p>6 Q. You don't have -- you have a date</p> <p>7 range and then a total number of hours with a</p> <p>8 charge?</p> <p>9 A. Okay.</p> <p>10 Q. Right? So there's no way to determine</p> <p>11 whether Mr. Romano charged any time for reviewing</p> <p>12 this deposition transcript?</p> <p>13 A. There would be if you looked at the</p> <p>14 bills associated with him.</p> <p>15 Q. Do you have those?</p> <p>16 A. Yes.</p> <p>17 Q. May I see those? Are these marked?</p> <p>18 MS. CARTER: They are all in that</p> <p>19 same.</p> <p>20 BY MR. ANDERTON:</p> <p>21 Q. All in that same folder? Do you have</p> <p>22 Mr. Romano's bills beyond April and May?</p> <p>23 A. I believe that should be complete.</p> <p>24 That's what my wife gave me, Denise.</p> <p>25 Q. This is not complete. It stops at</p>
<p style="text-align: right;">Page 563</p> <p>1 deposition transcripts from Plaintiff's counsel on</p> <p>2 just that subject, and Mr. Romano receives them and</p> <p>3 then that subject ends up in the final version of</p> <p>4 the report, but he wasn't doing anything?</p> <p>5 A. He did not do a thing with that,</p> <p>6 nothing.</p> <p>7 Q. Just coincidence?</p> <p>8 A. There's nothing coincidental about it.</p> <p>9 He did not review those documents. I did. I was</p> <p>10 the one who looked at them objectively and entered</p> <p>11 my opinion.</p> <p>12 Q. Will you get your billing records out,</p> <p>13 please?</p> <p>14 A. Yeah. Do you have them or do I have</p> <p>15 them?</p> <p>16 Q. I don't have them.</p> <p>17 A. Okay.</p> <p>18 Q. Mr. Kenny, will you find your billing</p> <p>19 records for June?</p> <p>20 A. May, June.</p> <p>21 Q. You got them?</p> <p>22 A. Yes.</p> <p>23 Q. May I see them very quickly?</p> <p>24 A. Sure. (Hanging).</p> <p>25 Q. In looking at these, I now realize</p>	<p style="text-align: right;">Page 565</p> <p>1 May 9 for Mr. Romano?</p> <p>2 A. Then May 9 may have been the last time</p> <p>3 that he billed.</p> <p>4 Q. Well, the document I just looked at</p> <p>5 stops at May 10 actually. So sir, we don't have the</p> <p>6 time sheet -- according to invoice 1032, there's a</p> <p>7 time sheet for Mr. Romano for the period May 11 to</p> <p>8 June 15 and the detail sheets you've just given me</p> <p>9 don't go past May 10, so that actually fits. Do we</p> <p>10 have those time sheets?</p> <p>11 A. I don't have those time sheets.</p> <p>12 Q. Okay. Will you make a note to</p> <p>13 yourself to track those down and get those to</p> <p>14 Plaintiff's counsel?</p> <p>15 A. Okay. Time sheets for what?</p> <p>16 Q. Mr. Romano's detailed time sheets for</p> <p>17 any time after May 10, 2010.</p> <p>18 A. Post, I'm sorry?</p> <p>19 Q. Post May 10, 2010.</p> <p>20 A. Okay.</p> <p>21 Q. Now, Mr. Kenny, I'm looking at</p> <p>22 Mr. Romano's time sheets, and on April 10, 2010, he</p> <p>23 charged one hour for what he characterized a draft</p> <p>24 report.</p> <p>25 A. I don't know what that was. What date</p>

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<p style="text-align: right;">Page 566</p> <p>1 was it?</p> <p>2 Q. April 10.</p> <p>3 A. I don't know.</p> <p>4 Q. On April 27, he charged an hour -- I'm</p> <p>5 sorry -- on April 26th, he charged five and a half</p> <p>6 hours, and the time actually says write draft number</p> <p>7 one of report?</p> <p>8 A. Okay. He was doing his own work.</p> <p>9 Q. Were you also writing parallel drafts?</p> <p>10 A. Were we writing parallel -- if you</p> <p>11 could use that term, yes, I guess so.</p> <p>12 Q. So you wrote a draft and he wrote a</p> <p>13 draft?</p> <p>14 A. He made some notes and gave them to</p> <p>15 me.</p> <p>16 Q. This says write draft number one of</p> <p>17 report?</p> <p>18 A. Yes.</p> <p>19 Q. Is that making notes?</p> <p>20 A. Yes, it was very cryptic of which he,</p> <p>21 I believe, cut and pasted them into my document when</p> <p>22 I was there.</p> <p>23 Q. Do you have the time detail sheets for</p> <p>24 your time for this period?</p> <p>25 A. I don't know. You have what I have.</p>	<p style="text-align: right;">Page 568</p> <p>1 report.</p> <p>2 A. He was drafting -- something, I'm not</p> <p>3 sure what he was drafting.</p> <p>4 Q. Well, so on April -- well, he spent</p> <p>5 five and a half hours on it. That sounds like a</p> <p>6 little more than notes?</p> <p>7 A. Well, he drafted something.</p> <p>8 Q. You were charging plaintiff's counsel</p> <p>9 \$430 an hour?</p> <p>10 A. He was charging them and he was</p> <p>11 working on the report.</p> <p>12 Q. \$430 an hour?</p> <p>13 A. Yes.</p> <p>14 Q. So five and a half hours is \$2300 or</p> <p>15 so?</p> <p>16 A. Yes.</p> <p>17 Q. Does that sound about right, maybe</p> <p>18 even a little more than that?</p> <p>19 A. Yes.</p> <p>20 Q. And he told Plaintiff's counsel that</p> <p>21 he was writing a draft of the report, and that</p> <p>22 that's what they were paying him \$2300 for. You're</p> <p>23 now saying he wasn't doing that?</p> <p>24 A. I don't know what he was doing.</p> <p>25 MS. CARTER: Objection.</p>
<p style="text-align: right;">Page 567</p> <p>1 Q. Well, what I don't have is any detail</p> <p>2 for. You see how this has the description of</p> <p>3 services for Mr. Romano? I don't have any of those</p> <p>4 for you. I have only invoices.</p> <p>5 A. I should have those. I have them.</p> <p>6 Q. Do you have those?</p> <p>7 A. If they are not there, no, I don't</p> <p>8 have them with me.</p> <p>9 Q. Actually, I misspoke. I do have some</p> <p>10 of yours. My apologies, Mr. Kenny. I didn't look</p> <p>11 at it closely enough. So I'm looking at your time</p> <p>12 sheets now, I do have them, detailed time sheets.</p> <p>13 And I start with the date of February 26, which is</p> <p>14 the earliest entry which is consistent with the fact</p> <p>15 that you said earlier it was around the 23rd or</p> <p>16 fourth when you first got documents from Plaintiff's</p> <p>17 counsel. And as I look at your time entries all the</p> <p>18 way through the end of April, I don't see any</p> <p>19 drafting by you. Is that accurate?</p> <p>20 A. From when to when?</p> <p>21 Q. From February through April 24, 2010.</p> <p>22 I see no drafting by you?</p> <p>23 A. No. I did drafting. I did drafting</p> <p>24 of the tables. I started on the tables.</p> <p>25 Q. While Mr. Romano was drafting the</p>	<p style="text-align: right;">Page 569</p> <p>1 A. He gave my wife the bills, and they're</p> <p>2 sent out.</p> <p>3 BY MR. ANDERTON:</p> <p>4 Q. And he gave you the draft of the</p> <p>5 report for you to review as well, right?</p> <p>6 A. He gave me the draft of a report, no,</p> <p>7 we sat down to review that report. We -- we sat</p> <p>8 down to review what he had done.</p> <p>9 Q. Okay. The next day, he charged</p> <p>10 another hour and a half for what he characterized as</p> <p>11 work on report. Two days after that, he charged</p> <p>12 three hours, again, work on report. The following</p> <p>13 week, May 4, he charged a half hour, work on report.</p> <p>14 That's ten and a half hours that he's characterized</p> <p>15 as drafting and working report. You say he's not</p> <p>16 doing any drafting?</p> <p>17 A. I'm not sure what he's doing. I know</p> <p>18 he was at one point going to try to do the footnotes</p> <p>19 or the references.</p> <p>20 Q. So the first draft that you produced</p> <p>21 indicated that he was drafting and going to testify.</p> <p>22 His time records are consistent with that?</p> <p>23 A. Uh-huh.</p> <p>24 Q. And you somehow are begging off that</p> <p>25 and saying he wasn't doing that actually?</p>

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<p style="text-align: right;">Page 570</p> <p>1 MS. CARTER: Objection.</p> <p>2 A. I don't know what he did. I don't</p> <p>3 know what he was working on.</p> <p>4 BY MR. ANDERTON:</p> <p>5 Q. Well, we know exactly what he did. We</p> <p>6 have a draft report that indicates he was -- it was</p> <p>7 drafted by him in April and early May, right?</p> <p>8 MS. CARTER: Objection.</p> <p>9 BY MR. ANDERTON:</p> <p>10 Q. Is that right?</p> <p>11 A. Yes, that's what the records state.</p> <p>12 Q. Okay. You don't have any reason to</p> <p>13 believe these records are falsified, do you?</p> <p>14 A. No. I have no reason to believe that.</p> <p>15 Q. I would be very curious to see those</p> <p>16 additional time sheets from Mr. Romano, and I don't</p> <p>17 think yours are in here as well, okay?</p> <p>18 A. Yeah.</p> <p>19 Q. Past May.</p> <p>20 A. I'm sorry. What am I looking for?</p> <p>21 Q. Your detailed time sheets for time</p> <p>22 beyond May 10?</p> <p>23 A. They are not there?</p> <p>24 Q. Neither of your detailed time sheets</p> <p>25 are here. The latest entry for either one of you is</p>	<p style="text-align: right;">Page 572</p> <p>1 product X that is adulterated, could you do that</p> <p>2 analysis without looking at the process validation?</p> <p>3 A. Could I do it? I could if I found</p> <p>4 instances where adulteration occurred, but I don't</p> <p>5 need that because I could do it by exception. If I</p> <p>6 saw falsified results, if I saw, let's say results</p> <p>7 in a record that are not specification when in fact</p> <p>8 they accepted it. It doesn't meet specification.</p> <p>9 So I don't need to look at validation in order to</p> <p>10 find exceptions to determine whether it violates</p> <p>11 GMP.</p> <p>12 Q. Would you ask to see the process</p> <p>13 validation?</p> <p>14 A. Yes.</p> <p>15 Q. Back to a point I made a moment ago,</p> <p>16 the process validation is significant because it's</p> <p>17 somewhat of a foundation for whether you have</p> <p>18 developed and created a process that is capable of</p> <p>19 consistently manufacturing product within</p> <p>20 specification, right?</p> <p>21 A. I wouldn't phrase it that way, but</p> <p>22 it's very important as part of the development</p> <p>23 process and the commercialization process.</p> <p>24 Q. Okay. In fact, the commercialization</p> <p>25 process cannot go forward without a validated</p>
<p style="text-align: right;">Page 571</p> <p>1 May 10. You'll track those down?</p> <p>2 A. Absolutely.</p> <p>3 Q. Thank you very much.</p> <p>4 In earlier deposition on June 29, you</p> <p>5 talked about process validation, and Mr. Moriarty</p> <p>6 asked you questions about whether you looked at</p> <p>7 process validation. Do you remember that testimony?</p> <p>8 A. Yes. Yes.</p> <p>9 Q. As somebody who is evaluating</p> <p>10 whether -- or at least the likelihood, of whether</p> <p>11 adulterated product was produced, process validation</p> <p>12 is a pretty critical document, isn't it?</p> <p>13 A. It's a portion of that, yes.</p> <p>14 Q. So it's a very important document,</p> <p>15 isn't it?</p> <p>16 A. Yes.</p> <p>17 Q. In fact, it's kind of the jumping off</p> <p>18 point for the whole analysis, isn't it?</p> <p>19 A. No, I wouldn't call it that. It's</p> <p>20 like everything else, it's an important step in the</p> <p>21 development process, in the commercialization</p> <p>22 process.</p> <p>23 Q. If you were hired by a pharmaceutical</p> <p>24 manufacturer today and they said, Mr. Kenny, we'd</p> <p>25 like you to evaluate whether we have produced any of</p>	<p style="text-align: right;">Page 573</p> <p>1 process; is that right?</p> <p>2 A. That is correct.</p> <p>3 Q. If the FDA came in and did an audit</p> <p>4 and determined that your process wasn't validated,</p> <p>5 they would do whatever they could to make you stop</p> <p>6 making that product almost immediately, wouldn't</p> <p>7 they?</p> <p>8 A. Correct.</p> <p>9 Q. But you didn't look at the process</p> <p>10 validations for DIGITEK in this litigation, did you?</p> <p>11 A. I did not go into detail on those.</p> <p>12 Q. You saw the .5 milligram process</p> <p>13 validation, but did not ask for the other process</p> <p>14 validations, did you?</p> <p>15 A. I apparently did not ask for them,</p> <p>16 yes. I really don't recall, quite honestly.</p> <p>17 Q. Do you have any reason to believe that</p> <p>18 you actually asked for the additional process</p> <p>19 validations?</p> <p>20 A. I don't recall, honestly.</p> <p>21 Q. Well --</p> <p>22 A. But your question is again.</p> <p>23 Q. Do you have any reason to believe that</p> <p>24 you did asked for them?</p> <p>25 A. No recollection that I asked for them.</p>

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<p style="text-align: right;">Page 574</p> <p>1 Q. Okay. What did you ask, for 2 additional documents? I mean, we saw earlier that 3 you asked for batch records and didn't get them? 4 A. Uh-huh. 5 Q. Do you remember asking for and getting 6 anything other than the FDA documents that 7 plaintiffs thought were so important? 8 MS. CARTER: Objection. 9 A. The documents that were available to 10 me were on Crivella, and I was able to do a search 11 and try to find a document. If I couldn't find it, 12 it wasn't there. That was the database. So it 13 would be futile to ask for a document that didn't 14 exist because it was not there. 15 BY MR. ANDERTON: 16 Q. Do you remember the last time that you 17 were deposed giving testimony about an unsigned 18 memo? 19 A. There were several unsigned documents, 20 but yeah. 21 Q. Okay. I'm handing you a document that 22 has previously been marked as Plaintiff's Exhibit 23 317. Take a moment to look at that document. 24 A. Sure. 25 Q. Have you seen that document before?</p>	<p style="text-align: right;">Page 576</p> <p>1 unsigned version might be a draft? 2 A. Did I consider that, yes, I suppose I 3 did consider it. 4 Q. What did you do to satisfy yourself if 5 you considered it that it in fact wasn't a draft? 6 A. I did do anything in addition. 7 Q. So you're more than happy to supply 8 that scathing testimony about the GMP practices of 9 Actavis when you yourself didn't feel it was 10 necessary to do anything to satisfy your own logical 11 inquiry about whether that was the final version of 12 that document? 13 MS. CARTER: Objection. 14 A. I assumed that it was there. It was 15 the final document, the original was asked for, and 16 it did not exist. That was my assumption. I didn't 17 go and search to see if -- I don't know how I could 18 search for a document that -- a second document that 19 was signed versus one that was unsigned. 20 BY MR. ANDERTON: 21 Q. Do you know the nature of document 22 productions in litigations this large? 23 A. No. 24 Q. You don't know anything about how many 25 documents or whether drafts are produced or anything</p>
<p style="text-align: right;">Page 575</p> <p>1 A. Yes, I saw it as an unsigned document. 2 Q. As an unsigned document? 3 A. That's correct. 4 Q. And when you were deposed in June, you 5 testified about the unsigned document, didn't you? 6 A. Yes, I did. 7 Q. And you spoke pretty harshly about it, 8 didn't you? 9 A. I wouldn't use the term "harshly," I 10 made comment to it. 11 Q. Well, you said, and this is from page 12 277 of your prior deposition, "because the value, 13 even if it were a very logical explanation," that 14 it's not signed, is what you're referring to, "the 15 value of it is nill. It is a gross violation of 16 GMP, and how that document could have been created 17 and distributed and how anybody would have received 18 it and not kicked it back to the original person to 19 make sure it wasn't signed or dated is beyond me. 20 It's a total -- talk about a breakdown. This is a 21 significant breakdown." 22 That's a pretty harsh characterization, 23 isn't it? 24 A. Yes. 25 Q. Did you ever consider that the</p>	<p style="text-align: right;">Page 577</p> <p>1 like that? 2 A. No. 3 Q. You see the sticker on that document, 4 the 317, do you see the date on it? 5 A. Yes. 6 Q. What is it? 7 A. Well, it says underneath the Exhibit 8 number, 51410. 9 Q. That means that document was used as 10 an exhibit by plaintiff's counsel in a deposition on 11 May 14, 2010, a month before you finalized your 12 report, and a month and a half before you testified. 13 It was available to you, readily available. In 14 fact, plaintiffs had used it as an exhibit. You 15 didn't feel it was even worth asking them whether 16 that was a draft? 17 A. It wasn't a matter of asking them. I 18 saw the document, I assumed that that naturally was 19 the single document. I made an assumption. 20 Q. An obviously incorrect assumption? 21 MS. CARTER: Objection. 22 A. It turned out to be incorrect that it 23 did exist. 24 MR. ANDERTON: I want to consult with 25 Mr. Kaplan for a moment. We're going to go</p>

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Mark Kenny, Volume II

Videotaped

February 16, 2011

<p style="text-align: right;">Page 578</p> <p>1 out and take a break for a moment. I may be 2 done. 3 THE VIDEOGRAPHER: We're off the 4 record. The time is 6:10. 5 (Recess taken.) 6 THE VIDEOGRAPHER: I'm going to start 7 up in a minute. We're back on the record. 8 The time is 6:16. 9 MR. ANDERTON: I have no further 10 questions at this time. 11 MS. CARTER: I have just literally 12 three questions. 13 EXAMINATION BY MS. CARTER: 14 Q. Your final report which is Exhibit 48, 15 I believe somewhere around here, you agree with all 16 of the opinions in this report? 17 A. I absolutely do. 18 Q. You stand by all the opinions in the 19 report? 20 A. I stand by them all. 21 Q. And these opinions you believe are 22 within your area of expertise? 23 A. Yes, I do. 24 And can I make a statement that this 25 report was not signed I have to retract because it</p>	<p style="text-align: right;">Page 580</p> <p>1 C E R T I F I C A T E 2 3 S T A T E O F N E W Y O R K) 4 : S s 5 C O U N T Y O F D U T C H E S S) 6 7 8 I, Jane Watson, a Reporter and Notary 9 Public within and for the State of New York 10 do hereby certify: 11 That MARK KENNY, the witness whose 12 deposition is hereinbefore set forth, was duly 13 sworn by me and that such deposition is a true 14 record of the testimony given by such witness. 15 I further certify that I am not related 16 to any of the parties to this action by blood 17 or marriage, and that I am in no way 18 interested in the outcome of this matter. 19 IN WITNESS WHEREOF, I have hereunto set my 20 hand this 21st day of February, 2011. 21 _____ 22 JANE D. WATSON 23 24 25</p>
<p style="text-align: right;">Page 579</p> <p>1 indeed was signed. It doesn't mean that it's a 2 quality document, but indeed it was signed. 3 MR. ANDERTON: By "this," you're 4 talking about what we discussed as having 5 previously been marked as Plaintiff's 6 Exhibit 137? 7 THE WITNESS: Yes. 8 MS. CARTER: That's all I have. 9 MR. ANDERTON: No further questions. 10 THE VIDEOGRAPHER: This is the end of 11 the deposition of Mark Kenny. Today's date 12 is February 16, 2011. The time is 6:17. 13 We're off the record. 14 15 16 17 18 19 20 21 22 23 24 25</p>	

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